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In The

# Supreme Court of the United States

October Term, 1997

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,

*Petitioner,*

v.

ELI LILLY AND COMPANY,

*Respondent.*

**On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit**

## PETITION FOR A WRIT OF CERTIORARI

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## QUESTIONS PRESENTED

1. Did the Federal Circuit prejudicially err in upholding an order of the Judicial Panel on Multidistrict Litigation ("MDL") transferring a patent infringement action filed by the Regents of the University of California ("Regents") against Eli Lilly & Co. ("Lilly") from the Northern District of California to the Southern District of Indiana, over the Regents' objections and despite the Northern District's prior orders denying motions to transfer, when the cases consolidated by transfer had no common issue of material fact or law and the panel's reason for its 28 U.S.C. § 1407(d) transfer order was that each of the patent cases involved the use of recombinant DNA technology?

2. Did the District Court for the Southern District of Indiana violate 28 U.S.C. §§ 1407(a) and 1404 in the manner currently before this Court in *In re American Continental Corp./Lincoln Savings & Loan Securities Litigation*, 102 F.3d 1524 (9th Cir. 1996), *cert. granted in part sub nom. Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 117 S. Ct. 1818 (1997), by transferring venue to itself to try the Regents' action on the merits over the Regents' objections, instead of remanding the action to the Northern District of California as Section 1407(a) specifically requires?

3. As the Eleventh Amendment embodies the presupposition that each State is a sovereign entity in our federal system, is it a *per se* abuse of discretion for a federal court to use either 28 U.S.C. § 1404(a) or § 1407 to transfer a federal question lawsuit initiated by a State in a

## QUESTIONS PRESENTED – Continued

federal district court in that State, pursuant to the exclusive jurisdiction of the federal courts over the subject matter of the lawsuit, to a federal district court in another State without the State's consent?

## PARTIES

The parties are Petitioner Regents of the University of California and respondent Eli Lilly & Co.[1]

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[1] Pursuant to Rule 29.6, petitioner states that the Regents of the University of California have no parent companies or nonwholly owned subsidiaries.

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## OPINIONS BELOW

The opinions of the court of appeals are reported at 119 F.3d 1559 and 964 F.2d 1128. Copies of these opinions are annexed hereto as Appendix A and Appendix B respectively. The Federal Circuit's October 24, 1997 order denying rehearing is unpublished and annexed hereto as Appendix C. The district court's opinion on the merits is reported at 39 U.S.P.Q.2d (BNA) 1225. The Southern District of Indiana's order transferring this case to itself for trial dated March 2, 1994 is annexed hereto as Appendix D. The MDL panel's transfer order is annexed hereto as Appendix E.

## JURISDICTION

The judgment of the court of appeals was entered on July 22, 1997. The court of appeals denied the Regents' timely petition for rehearing and suggestion for rehearing *en banc* on October 24, 1997 (App. C at 58.) Jurisdiction of the district court was based on the exclusive federal jurisdiction over patent cases and on federal question jurisdiction. 28 U.S.C. §§ 1338(a), 1331. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1254(1).

## CONSTITUTIONAL AND STATUTORY PROVISIONS

The Eleventh Amendment to the United States Constitution provides:

> The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State.

The federal multidistrict litigation statute provides in relevant part:

> When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings. Such transfers shall be made by the judicial panel on multidistrict litigation authorized by this section upon its determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions. Each action so transferred shall be remanded by the panel at or before the conclusion of such pretrial proceedings to the district from which it was transferred unless it shall have been previously terminated: *Provided, however,* That the panel may separate any claim, cross-claim, counter-claim, or third-party claim and remand any of such claims before the remainder of the action is remanded.

28 U.S.C. § 1407(a).

The federal venue transfer statute provides in relevant part:

> For the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought.

28 U.S.C. § 1404(a).

## STATEMENT OF THE CASE

**Background Facts.** In 1977, scientists at the San Francisco campus of the University of California ("UC") made a groundbreaking discovery: the DNA sequence of preproinsulin, the biological precursor to insulin. Persons

then suffering from diabetes could control their symptoms only with injections of natural animal insulin extracted from the pancreases of pigs or cattle. The UC scientists' discovery paved the way for the production of recombinantly produced human insulin, which is cheaper, safer, and available in greater supply than extracted animal insulin. UC's discovery, as Lilly acknowledged below, "was the first successful cloning of an important animal hormone in a bacterium using recombinant DNA technology." That pioneer work generated tremendous excitement in academic research circles, in the private sector, and among the general public. To make the benefits of its discovery available to diabetics, UC entered into a partnership with Lilly, the market leader in producing and selling insulin. To protect its rights, UC also sought and received two United States patents for its insulin inventions. Within several years, the relationship between UC and Lilly soured. After obtaining the benefits of years of work by UC scientists, Lilly refused to enter into a license agreement with UC. Lilly continued to practice UC's invention and ultimately began to manufacture and market recombinant human insulin, whereby UC claimed its insulin patents were infringed.

**Litigation History.** The Regents of the University of California are an instrumentality of the State of California for Eleventh Amendment purposes.[1] Although the Regents selected the Northern District of California as the

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[1] (App. B at 50 [*In re Regents of the Univ. of Cal.*, 964 F.2d 1128, 1134 (Fed. Cir. 1992)]); *see also Hamilton v. Regents of the Univ. of Cal.*, 293 U.S. 245, 257 (1934) (University of California is constitutional department of State government); Cal. Const. art. IX, § 9(a).

forum for this case, the MDL panel transferred the action for pretrial purposes to the Southern District of Indiana, and the Indiana district court subsequently transferred the case to itself for trial. (App. E at 67; App. D at 63.) Both the MDL panel and the Indiana district court disregarded the Regents' right to select a forum and violated the plain language of the applicable transfer statutes: Sections 1407 and 1404.

The MDL transfer order consolidated for pretrial proceedings five patent actions involving the use of recombinant DNA technology to manufacture two different pharmaceutical drugs: insulin and human growth hormone. Two unrelated patent actions had been filed in 1990 by the Regents in the Northern District of California: (1) the instant case, *Regents of the University of California v. Eli Lilly & Co.*, C-90-03730-DLJ (N.D. Cal.) charging Lilly with infringing UC's insulin patents, and (2) *Regents of the University of California v. Genentech, Inc.*, C90-2232-RFP (N.D. Cal.) charging Genentech with infringing a different patent owned by UC by manufacturing human growth hormone; Genentech added Lilly (UC's exclusive licensee under that patent) to this second action by filing counterclaims. Three patent actions had been filed in Indiana: (1) *Genentech, Inc. v. Eli Lilly & Co. and Regents of the University of California*, IP 90-1679-C (S.D. Ind.), Genentech's declaratory relief action on the same UC growth hormone patent, filed one day before the Regents filed the mirror image infringement action in California; (2) *Eli Lilly & Co. v. Genentech, Inc.*, IP 87-219-C (S.D. Ind.); and (3) *Genentech, Inc. v. Eli Lilly & Co.*, IP 88-1463 (S.D. Ind.). The latter two cases involved thirteen Genentech patents and a dispute between Genentech and Lilly concerning license and trade secret agreements relating to

Genentech's and Lilly's manufacture of human growth hormone; the Regents were not a party to either.

The Regents' insulin suit against Lilly and the human growth hormone suits in Indiana and California involved different patents, products, infringers, and causes of action. The only similarity between the actions was that some of the same UC scientists were involved in UC's insulin and growth hormone inventions and that the patents in all five actions involved recombinant DNA technology. When Lilly sought consolidation of the five suits and transfer to Indiana from the MDL panel under Section 1407, all were at different stages in the litigation process. The Regents opposed Lilly's motion on the ground that transfer to Indiana would violate the Regents' sovereign rights; they also pointed out that their suit against Lilly concerned insulin patents while their suit against Genentech involved a different patent on growth hormone and that the Indiana actions between Lilly and Genentech, to which the Regents were not even a party, related to thirteen other patents, different products, and different circumstances.

Although the MDL panel recognized that commonality among the actions did not exist, it nevertheless concluded that they should be consolidated for pretrial proceedings because the pretrial court had to understand recombinant DNA technology. The panel tried to bolster its conclusion by saying that Indiana was more centrally located than California, that relevant documents and witnesses were likely to be found at Lilly's headquarters in Indiana, and that the Indiana courts had developed a familiarity with some of the issues in the Indiana litigation. (App. E at 65-67.) That determination was made despite Genentech's admission that no technology-based

motions had yet been decided in any of the cases pending in Indiana.

The MDL panel forced the transfer to Indiana even though the district court in the Northern District of California had denied two earlier transfer motions as well as Lilly's attempt to relate the two Northern District of California actions. The Northern District had denied Genentech's Section 1404(a) motion to move the Regents' suit against it to the Southern District of Indiana, because Indiana was not a more convenient forum and because the Indiana patent actions involved different patents and different infringing activity. *University of Cal. v. Eli Lilly & Co.*, 21 U.S.P.Q.2d (BNA) 1201, 1207-08 (N.D. Cal. 1991). The Northern District also had rejected a transfer motion by Lilly in the Regents' suit against Lilly, ruling that venue was properly laid in the Northern District. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 734 F. Supp. 911 (N.D. Cal. 1990). The Northern District had even denied Lilly's motion to relate the two California actions. *University of Cal.*, 21 U.S.P.Q.2d (BNA) at 1208.

Despite all the facts weighing against consolidation and transfer, the MDL panel transferred both the California patent cases to Indiana, albeit with the mild cautionary observation:

> It may be, on further refinement of the issues and close scrutiny by the transferee judge, that some claims or actions can be remanded in advance of the other actions in the transferee district.

(App. E at 66.) The Regents thereupon sought a writ of mandamus from the Court of Appeals for the Federal Circuit to vacate the MDL panel's transfer order, raising all of the issues heretofore mentioned. Based on a literal

reading of the text of the Eleventh Amendment and deference to the MDL panel, the Federal Circuit denied the writ. (App. B at 49-57 [*In re Regents*, 964 F.2d at 1134-37].)

Once the Regents' insulin case was before the Indiana court, Lilly moved pursuant to 28 U.S.C. § 1404(a) to transfer the case for trial on the merits to the Indiana district court. The Regents again objected. Following the unauthorized practice of self-transfer that this Court is reviewing in *In re American Continental Corp./Lincoln Savings & Loan Securities Litigation*, 102 F.3d 1524 (9th Cir. 1996), *cert. granted in part sub nom. Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 117 S. Ct. 1818 (1997) ("*Lexecon*"),[2] and notwithstanding the clear language of Section 1407(a) requiring remand, the Indiana court granted Lilly's motion. (App. D at 63.) The Indiana court then held a two-week bench trial on the Regents' claims, made numerous findings of fact, and in reliance on these findings found for Lilly on every disputed issue of infringement, validity and enforceability of the patents, including on Lilly's claim that UC scientists committed inequitable conduct to obtain its insulin patents. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 39 U.S.P.Q.2d (BNA) 1225 (S.D. Ind. 1995), *aff'd in part and rev'd in part*, 119 F.3d 1559 (Fed. Cir. 1997). The latter holding was the basis for a $20 million petition by Lilly for attorneys' fees and costs in the Indiana district court.

On appeal, the Federal Circuit affirmed the Indiana court's self-transfer order, rejecting the statutory language of § 1407(a) that required remand of the California

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[2] *Lexecon* was argued to this Court on November 10, 1997, but the decision has not come down as of the date this Petition is written.

cases to California as well as the language of § 1404(a) precluding self-transfer. It also rejected the Regents' constitutional arguments and arguments on the merits of the infringement and validity issues, reversing only on the inequitable conduct holdings because the Indiana district court had applied an incorrect legal standard on that issue. (App. A [119 F.3d 1559].) In affirming the Indiana district court's findings of invalidity and noninfringement, the Federal Circuit had to defer to the factual determinations made by the Indiana district court and could not remedy the prejudice the Regents suffered from litigating in a foreign jurisdiction. (*See id.* at 13-21, 26-33 [119 F.3d at 1566-69, 1571-74].)

## REASONS FOR GRANTING THE WRIT

**Introduction.** The questions presented are very important to the Nation as a whole, as well as to the parties, because they raise sensitive issues affecting federal and state sovereignty, the appropriate balance between interests in judicial efficiency and State sovereignty concerns, the limitations of federal judicial power imposed by Congress, and the protection of intellectual property that vitally impacts the national economy.

**The Regents were forced into federal court to protect their patents.** The Regents could not protect UC's patents by resorting to California's state courts because federal courts have exclusive subject matter jurisdiction of such controversies. 28 U.S.C. § 1338. In denying the Regents' mandamus petition and the appeal challenging the subsequent transfer of the California actions to Indiana, the Federal Circuit effectively held that by filing in the Northern District of California, the Regents consented

to venue in every federal court in the Nation. That holding disregards the intendments regularly given in favor of any plaintiff's choice of forum and shrinks the sovereignty concerns addressed in the Eleventh Amendment to dimensions incompatible with the intent of the constitutional draftsmen to confine federal power and to respect sovereignty of the States.

**Section 1391 does not diminish a State's sovereignty.** When a conflict exists between concern for judicial thrift and State sovereignty, parsimonious allocation of judicial time must yield to the principles of federalism and to comity. Nothing in 28 U.S.C. § 1391 suggests that Congress intended to confer power on an MDL panel to disregard a State's sovereign power to choose the federal forum for its patent cases. A State plaintiff's choice of forum should be dispositive in light of constitutional deference to State sovereignty and the preservation of the delicate balance between federal and State power that this Court has repeatedly recognized.[3]

**The Indiana district court's self-transfer is contrary to Section 1407(a)'s plain meaning and legislative history.** The text and the legislative history of Section 1407(a) explicitly demonstrate that Congress never intended a court to which an MDL panel had transferred

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[3] *See Seminole Tribe v. Florida*, 517 U.S. 44, 116 S. Ct. 1114, 1122 (1996) ("[E]ach State is a sovereign entity in our federal system."); *Trainor v. Hernandez*, 431 U.S. 434, 441 (1977); *Younger v. Harris*, 401 U.S. 37, 44 (1971) (describing "comity" as "a proper respect for state functions, a recognition of the fact that the entire country is made up of a Union of separate state governments, and a continuance of the belief that the National Government will fare best if the States and their institutions are left free to perform their separate functions in their separate ways").

a case for pretrial purposes to transfer to itself the trial on the merits. The statute dictates that the action "shall be remanded" to the court from which the case was multi-districted "at or before the conclusion of . . . pretrial proceedings." 28 U.S.C. § 1407(a). The history repeatedly states that that section "would not affect the place of trial in any case." H.R. Rep. No. 1130, 90th Cong., *reprinted in* 1968 U.S.C.C.A.N. 1898, 1900. Unlike the MDL panel and the Indiana court, Congress respected the right of plaintiffs to choose the venue in which their cases will be tried on the merits. The conduct of the MDL panel and of the Indiana district court in this case gives substance to Judge Kozinski's conclusion that some judges have

> parlayed a narrow grant of authority to conduct consolidated discovery into a mechanism for systematically denying plaintiffs the right to trial in their forum of choice.

*Lexecon*, 102 F.3d at 1540 (Kozinski, J., dissenting). When the plaintiff is a State this error rises to constitutional magnitude.

**As in *Lexecon*, the Indiana district court's self-transfer did not make the forum more convenient.** Although all federal district courts have the same powers (as well as the same restrictions on power), each federal district, each federal judge, and juries in the various districts have characteristics of their very own. Even for a non-sovereign plaintiff, the presumption in favor of the plaintiff's choice of forum is strong; it can only be defeated by a compelling showing that the convenience of parties and witnesses will be thereby served. *E.g.*, *Gulf Oil Corp. v. Gilbert*, 330 U.S. 501, 508 (1947).

Here, as in *Lexecon*, a venue transfer of the Regents' insulin litigation from California to Indiana for trial was not and should never have been granted under ordinary

Section 1404(a) standards. No Indiana witnesses testified at trial. The only convenience that might have been served was Lilly's, because its headquarters are located in Indiana, an atmosphere that Lilly deemed more advantageous to its litigation strategy than California. Here, also as in *Lexecon*, the transferee court concluded that judicial resources would be wasted if a California district court conducted the trial of the California litigation, despite the lack of any evidence that the Indiana judge knew more about basic principles of biotechnology than the Northern District of California, whose jurisdiction encompasses major research universities, public and private, and a large collection of biotechnology companies.

**The Federal Circuit disregarded sovereignty concerns.** The Federal Circuit further erred, on mandamus pre-trial and on post-trial appeal, in rejecting the Regents' Eleventh Amendment argument on the ground that the text of the Amendment did not embrace suits brought by a State plaintiff and therefore could not protect the Regents' case from being forcibly transferred to the Southern District of Indiana, where the Regents had never consented to litigate. In both decisions, the panel relied solely on *United States v. Peters*, 9 U.S. (5 Cranch) 115 (1809), and a narrow reading of the text of the Eleventh Amendment. (App. A at 7-9 [119 F.3d at 1564-65]; App. B at 51-53 [*In re Regents*, 964 F.2d at 1134-35].) The *Peters* case does not justify either decision; multidistricting and self-transfer were as remote from the 1809 Supreme Court's concern as an ICBM is from a musket.

The Federal Circuit disregarded this Court's decisions in *Seminole Tribe v. Florida*, 517 U.S. 44, 116 S. Ct. 1114 (1996), *Pennhurst State School & Hospital v. Halderman*, 465 U.S. 89 (1984), and *Port Authority Trans-Hudson*

*Corp. v. Feeney*, 495 U.S. 299 (1990), which do not restrict State sovereignty principles to the text of the Eleventh Amendment and which recognize the close connection between venue and sovereignty issues. In rejecting the Regents' Eleventh Amendment argument on mandamus, the court deemed "abstract" the Regents' concern that the transferee court might inject itself into the trial on the merits. The Federal Circuit derided the Regents' sovereignty concerns as a supposedly illegitimate attempt to use the Eleventh Amendment to give "procedural advantage to State litigants," (App. B at 52 [*In re Regents*, 964 F.2d at 1134]), ignoring the fact that sovereigns have rights that private litigants do not, including the absolute right to choose their forums. To the Federal Circuit, supposed judicial efficiency in transferring the unrelated cases to Indiana justified the MDL panel's order without any consideration of the Regents' forum choice or respect for dual sovereignty. On appeal post-trial, after the Indiana district court's self-transfer had proven that the Regents' concerns were not abstract at all, the Federal Circuit brushed the issue aside again. According to the Federal Circuit, the pretrial experience the Indiana court gained through the wrongful consolidation justified leaving the case where it never should have been in the first place.

## I. THE FEDERAL CIRCUIT PREJUDICIALLY ERRED IN UPHOLDING THE MDL TRANSFER ORDER BECAUSE NO COMMON QUESTIONS OF FACT OR LAW WERE PRESENTED.

Modern biotechnology cases require an understanding of recombinant DNA technology, but that understanding is not a material common fact within the meaning of Section 1407. If the common fact requirement

of Section 1407 were to be stretched to embrace recombinant DNA technology in biotechnology cases, then all patent cases simultaneously pending in the biotechnology field could be consolidated into one mega-pretrial bundle – a result inconsistent with congressional intent and the efficient administration of justice.

An analogous question was presented in *In re Repetitive Stress Injury Litigation*, 11 F.3d 368, 373 (2d Cir. 1993), in which the court issued a writ of mandamus to prevent a district court from consolidating numerous repetitive stress injury cases because the sole common "fact" – the same kind of injury – was so general that it encompassed many different ailments with numerous possible causes. That court cautioned that courts had to resist the "systemic urge" to aggregate litigation when consolidation erodes dedication to individual justice. *Id.* That seventeen different patents use recombinant DNA techniques is no more a common fact within the meaning of the statute than the practice of surgery is a common fact warranting consolidation of medical malpractice cases pending in different district courts when the cases variously involve appendectomies, hip replacements, and brain surgeries. Moreover, judicial thrift was never intended by Congress to justify an MDL panel's disregard for a sovereign State's federal forum choice, especially when the only system it can choose is federal and it has never intentionally waived its prerogative.

Even if the issue had been whether the MDL panel had abused its discretion, rather than exceeding its statutory authority, the record before the Federal Circuit pointed unerringly to that abuse. The California insulin and growth hormone cases had little to do with one another and nothing to do with the Indiana cases

between Genentech and Lilly except for some overlap of parties and the use of basic scientific technology. The Northern District of California had already decided that venue for all purposes was properly set in California. The excuse for consolidation was flimsy, and the panel gave no consideration to the countervailing interests in federalism, comity, or individual justice. Abstention from using federal power is a well-known lubricant for dual sovereignty and intercourt territorial frictions. Despite the frequency with which such issues now arise in the context of multidistrict litigation, this Court has not yet given guidance to the federal judiciary and to litigants on these increasingly important conflicts in multidistrict cases.

## II. THE FEDERAL CIRCUIT PREJUDICIALLY ERRED IN UPHOLDING THE INDIANA DISTRICT COURT'S ORDER TRANSFERRING THE REGENTS' INFRINGEMENT ACTION TO ITSELF FOR TRIAL.

The retention of the California litigation for trial on the merits not only violated the terms of Section 1407(a), it was also improper and unjustified under Section 1404(a) and, as discussed below, a violation of the State's sovereign rights and of every plaintiff's highly regarded right to choose the forum for its action. However, the Federal Circuit held that the Indiana court did not abuse its discretion by transferring the Regents' litigation to itself for trial on the merits over the Regents' objection. The Federal Circuit also erroneously held that the Regents waived any challenge under Section 1407(a) to

the district court's self-transfer by not specifically arguing that issue in their opening brief on appeal. (App. A at 11-12 [119 F.3d at 1565-66].)

**No Waiver Existed.** The Regents sufficiently raised the self-transfer problem in their opening brief by arguing that the Indiana court abused its discretion in transferring venue to itself under Section 1404(a). As explained by the *Lexecon* petitioner, the language of Section 1404(a) requiring transfer to an "other district," as well as the text of Section 1407(a), precludes self-transfer. The Regents brought the Ninth Circuit's intervening decision in *Lexecon* and Judge Kozinski's dissent therein to the Federal Circuit's and Lilly's attention before oral argument. The court had issued an order granting both parties additional argument time to address the venue and Eleventh Amendment questions. During oral argument, the panel debated whether the appropriate remedy for a district court's violating Sections 1407(a) and 1404(a) would be to vacate the trial judgment. It then avoided this difficult issue entirely by relying on the nonexistent waiver, although the propriety of the transfer was clearly at issue and Lilly had notice before oral argument that the 1407(a) argument raised in *Lexecon* was at issue here and ample opportunity to be heard on the issue.

The Federal Circuit's discovery of a waiver of the point is particularly indefensible because that court was thoroughly aware that throughout the litigation, in California, Indiana, and before the Federal Circuit itself, the Regents had consistently argued that the transfer to the Southern District of Indiana was improper. Moreover, when the opening brief was filed, every circuit and district court to address the issue had held that self-transfer under Section 1404(a) was permissible, notwithstanding

the language of Section 1407(a) and Section 1404(a).[4] It was not until this Court granted *certiorari* in *Lexecon* that it signaled potential disagreement with the uniform interpretation of Section 1407(a) and Section 1404(a) by the lower courts. Although the Regents promptly notified the Federal Circuit that *certiorari* had been granted in *Lexecon* before its decision was handed down, the Federal Circuit nevertheless chose to decide the case without awaiting this Court's *Lexecon* decision.

Even if the Federal Circuit was within its discretion in failing to decide whether the Indiana district court's actions violated the plain language of Section 1407(a), review by this Court is proper in light of *Lexecon*. As stated in *Lebron v. National R.R. Passenger Corp.*, 513 U.S. 374 (1995):

> Our traditional rule is that once a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they made below. [Petitioner's] contention . . . is . . . not a new claim within the meaning of that rule, but a new argument to support what has been his consistent claim. . . .

*Id.* at 379 (citations and quotation omitted). While arguing in the lower courts, the petitioner in *Lebron* had expressly

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[4] *See, e.g., Washington Pub. Util. Corp. v. United States Dist. Court*, 843 F.2d 319 (9th Cir. 1987); *In re Fine Paper Antitrust Litig.*, 685 F.2d 810 (3d Cir. 1982); *Pfizer, Inc. v. Lord*, 447 F.2d 122 (2d Cir. 1971); *In re Tax Refund Litig.*, 723 F. Supp. 922 (E.D.N.Y. 1989); *In re Dow Co. "Sarabond Prods." Liab. Litig.*, 664 F. Supp. 1403 (D. Colo. 1987); *In re Viatron Computer Sys. Corp. Litig.*, 86 F.R.D. 431 (D. Mass. 1980); *In re Penn Cent. Commercial Paper Litig.*, 62 F.R.D. 341 (S.D.N.Y. 1974); *Greyhound Computer Corp. v. IBM*, 342 F. Supp. 1143 (D. Minn. 1972).

disavowed an issue that this Court nevertheless decided, because it was "but a new argument to support what ha[d] been his consistent claim." *Lebron*, 513 U.S. at 379. The Regents never disavowed their venue arguments and they maintained throughout this litigation that venue in the Southern District of Indiana was improper.

**Section 1407(a) explicitly requires remand.** Congress could scarcely have been more lucid in stating its intent in Section 1407(a) that pretrial proceedings consolidated under the multidistrict litigation statute shall be remanded at the conclusion of the pretrial proceedings "to the district from which it was transferred." The statute does not give any discretion to the transferee court to do otherwise. Despite the plain language and clear legislative history of Section 1407(a), and despite the text of Section 1404(a), which permits transfer only to any "other" district, the Indiana court granted Lilly's request that it transfer the case to itself. (App. D at 63.) That precise error is before this Court in *Lexecon*.

## III. THE FEDERAL CIRCUIT'S SUPERFICIAL TREATMENT OF THE ELEVENTH AMENDMENT AND SOVEREIGNTY ISSUES WAS ERRONEOUS AND COULD DETRIMENTALLY AFFECT STATE UNIVERSITIES NATIONWIDE.

Totally apart from the statutory directives of Sections 1407 and 1404, Eleventh Amendment and sovereignty concerns barred the transfer of this action to any court to which the State plaintiff did not consent. In denying the Regents' appeal, the Federal Circuit summarily concluded that the Eleventh Amendment did not apply to suits brought by a State as a plaintiff and therefore did not protect the Regents' litigation from being forcibly

transferred for trial to the Southern District of Indiana, a forum in which the State of California never consented to litigate. The Federal Circuit relied solely on an 1809 Supreme Court case, *United States v. Peters*, 9 U.S. (5 Cranch) 115 (1809), and on a narrow reading of the Eleventh Amendment to restrict its applicability to suits "against" a State. (App. A at 7-9 [119 F.3d at 1564-65].)

The Federal Circuit's literal analysis conflicts sharply with the principle often reiterated by this Court that the Eleventh Amendment "stand[s] not so much for what it says, but for the presupposition . . . which it confirms," including the principle "that each State is a sovereign entity in our federal system." *Seminole Tribe*, 116 S. Ct. at 1122; *see Hans v. Louisiana*, 134 U.S. 1 (1890). The Federal Circuit simply assumed that because the State here was the plaintiff and the Eleventh Amendment referred to suits "against" a State, no further analysis was necessary. The court utterly failed to come to grips with the specific question presented here: Do the sovereignty concerns reflected by the Eleventh Amendment preclude transfer of a patent action brought by a State plaintiff in the exclusive jurisdiction of the federal district court from the venue chosen by the State to a different venue to which the sovereign did not consent?

Because the Federal Circuit decided that the Eleventh Amendment was not relevant at all, it did not consider whether the Regents had consented to be transferred for trial to a different federal court by filing in the Northern District of California. This Court has taught that a court must first decide whether a State unequivocally waived its sovereign rights. *Pennhurst*, 465 U.S. at 99; *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 239-40 (1985). Then, the court must determine the extent of the State's waiver.

*Port Auth.*, 495 U.S. at 306-08; *Beers v. Arkansas*, 61 U.S. (20 How.) 527, 529-30 (1858). The Federal Circuit failed to heed this Court. A proper application of this Court's precedent should have compelled a determination that the State waived its sovereign rights only with respect to litigation in the Northern District of California.

Because the Federal Circuit has nationwide jurisdiction over appeals from patent cases, 28 U.S.C. §§ 1292(c), 1295, that court's decision, if not reversed, will negatively affect State universities and research centers across the country. By taking this case and overturning the Federal Circuit's decision, this Court can prevent the chilling influence the decision could have on scientific research in this country. Cutting-edge technology and scientific discoveries drive the United States economy. With the passage of the Bayh-Dole Act of 1980, Pub. L. No. 96-517, § 6 (a), 94 Stat. 3019, Congress sought to further economic growth by using the patent system to encourage the commercial development of university inventions. *See* 35 U.S.C. § 200 *et seq.* State universities across the nation conduct basic research which advances this country's scientific knowledge and often results in patentable inventions.[5] In these days of diminishing public resources available to universities, these institutions often patent their discoveries to create income from their patent portfolios to finance additional, ongoing basic research.[6]

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[5] UC, for example, is the owner of over 1300 United States patents. University of Cal. Technology Transfer Program, *1997 Annual Report* 8. In 1997 alone, the UC system had 206 patents issue. *Id.*

[6] UC has an extensive licensing program, which generated $74.7 million in licensing revenues in fiscal year 1997. A portion of this income goes to the scientists responsible for the innovation, and the net after administrative costs goes to the UC

The Federal Circuit's narrow construction of the Eleventh Amendment will diminish a State's ability to protect its patent rights. A State university filing an infringement suit in a federal district court (as it must) within the State now risks the indignity of transfer to distant and less favorable forums where the lawsuit could not have been brought without the State's consent. Sovereignty principles should give a State the right to protection against these risks. Without this Court's intervention, the Federal Circuit will continue to misconstrue the significance of the Eleventh Amendment to the detriment of State patent holders. The lower court's jurisdictional errors merit resolution by this Court. *See United States v. Hohri*, 482 U.S. 64, 68 (1987); *Ex parte New York*, 256 U.S. 490, 497 (1921) (characterizing the Eleventh Amendment as a "fundamental rule of jurisprudence").

### A. The Federal Circuit Erred in Limiting the Eleventh Amendment Strictly to its Text.

The doctrine of sovereign immunity as embodied in the Eleventh Amendment plays a "vital role" in "our federal system." *Pennhurst*, 465 U.S. at 99. Over the years this Court has interpreted the scope of the Eleventh Amendment's protection to extend far beyond the literal language of the Amendment:

> [W]e long have recognized that blind reliance upon the text of the Eleventh Amendment is "to

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campuses to support ongoing research and educational programs. University of Cal. Technology Transfer Program, *1997 Annual Report* 3, 12.

> strain the Constitution and the law to a construction never imagined or dreamed of."

*Seminole Tribe*, 116 S. Ct. at 1130 (quoting *Principality of Monaco v. Mississippi*, 292 U.S. 313, 326 (1934), quoting *Hans v. Louisiana*, 134 U.S. at 15).

This Court's delineation of the breadth of Eleventh Amendment protection, commencing with *Hans*, contrasts sharply with the Federal Circuit's narrow, wooden construction of the Amendment. In *Hans*, the Court held that the Eleventh Amendment provided immunity to Louisiana in a suit brought against the State in federal court by a Louisiana citizen. Although the text of the Amendment is limited to suits brought by non-citizens of the State, it would be contrary to the principle of sovereign immunity and the intent of the drafters of the Amendment to permit citizens of a State to sue the State in federal court, while prohibiting suits by citizens of other States or foreign States. *Hans*, 134 U.S. at 15-17.

Similarly, this Court has ruled that the Eleventh Amendment bars suits by a foreign sovereign against a State, although the text of the Amendment only refers to suits brought by *citizens* of foreign States. "Manifestly we cannot . . . assume that the letter of the Eleventh Amendment exhausts the restrictions upon suits against nonconsenting States." *Principality of Monaco*, 292 U.S. at 322; *see id.* at 330. The Court concluded that the same fundamental principle which immunizes States from suits brought by citizens or subjects of another State applies to suits "against a State by a foreign State." *Id.* at 330.

This Court's Eleventh Amendment jurisprudence concentrates on the principles underlying the Amendment, rather than restricting its scope to a literal reading of the language of the Amendment. Although the

Amendment refers only to suits in law or equity, the Court has held that the Amendment nevertheless precludes admiralty suits against a State. *Id.* at 322 (citing *Ex parte New York*, 256 U.S. at 498). Similarly, despite the Amendment's references to suits by citizens of other States or foreign states, the Court has ruled that the Amendment bars suits against a State "brought by a corporation created by Act of Congress." *Id.* (citing *Smith v. Reeves*, 178 U.S. 436 (1900)). This broad construction has continued up to the present day, with this Court holding that the Eleventh Amendment prevents suits by Indian tribes against the United States. *Blatchard v. Native Village of Noatak*, 501 U.S. 780, 781-82 (1991).

In stark contrast to this Court's analysis, the Federal Circuit here focused myopically on the precise words of the Eleventh Amendment instead of examining the broad principles underpinning the Amendment. The Federal Circuit relied only on dicta in *Peters*, 9 U.S. (5 Cranch) at 139, which was decided more than 80 years before *Hans* began this Court's careful construction of the breadth of the Eleventh Amendment, and which on its facts is totally inapposite here. *Peters* did not involve a State plaintiff, an involuntary venue transfer of a State party, or even a State as a party at all. That case involved an act passed by the Pennsylvania legislature directing the governor of Pennsylvania to take all steps necessary – including calling out an armed force – to prevent execution of an admiralty decree stemming from an action brought by private individuals against the heirs of a deceased State treasurer. The inspiration for this extraordinary legislation was the State's belief that it had a claim to the property because the treasurer had held it for the State during his lifetime, although the State had not asserted

the claim in the action. The actual holding of *Peters* is that the Eleventh Amendment cannot be used to deprive a federal court of otherwise proper jurisdiction over an admiralty suit between private individuals because a nonparty State also has a claim to the proceeds of a prize cargo. Nothing in the opinion even remotely teaches that a State plaintiff may be involuntarily transferred from one federal jurisdiction to another – the question at issue here.

### B. The Involuntary Transfer of a State Plaintiff from Its Chosen Federal Forum Violates the Eleventh Amendment and Sovereignty Concerns.

If the Federal Circuit had grappled with the concept of sovereign immunity, rather than mechanically applying the literal language of the Eleventh Amendment, the court would have understood that the involuntary transfer of the Regents' action raises sovereignty concerns and implicates the Eleventh Amendment and associated principles of federalism. When the federal courts have exclusive jurisdiction over a given subject matter, such as patent disputes, a State seeking to enforce its rights must submit to the jurisdiction of the federal courts. Commencing an action in federal court does not connote the voluntary abandonment of a sovereign's usual right to litigate in its own courts. The State's only choices were to sue Lilly in federal court or to forfeit a public asset: the value of the royalties owed by Lilly as a result of Lilly's infringement of UC's patents. This decision to sue was not made lightly and its scope was limited to a suit in the Northern District of California. "[T]he problems of federalism inherent in making one sovereign appear against its will in the courts of the other" therefore are implicated by

this action. *See Pennhurst*, 465 U.S. at 99-100. In being transferred over its objections to Indiana, the State of California was forced to appear against its will in a foreign jurisdiction.

Moreover, the affirmative defenses raised herein (and typically raised in patent actions) underscore the fluid continuum between plaintiff and defendant roles in patent cases. In contrast to the usual federal case, the filing of an infringement suit places the patent owner in the role of defending its patent against allegations of invalidity and/or unenforceability. The inevitable assertion of such defenses forces the patent owner into the role of defendant in an action contesting its rights vis-a-vis the world with respect to the patent at issue. Unlike affirmative defenses that only prevent recovery on the plaintiff's specific cause of action, a final decision that an asserted patent is invalid or unenforceable means that the patent owner forfeits its intellectual property against the world.

Because the exclusive jurisdiction of the federal courts requires a State to enforce its patent property rights by suing in federal court, a subsequent transfer of a State's patent case to a federal court in another jurisdiction has the practical effect of forcing the State to defend its patent property in a jurisdiction never agreed to by the State. This case illustrates how a State patent plaintiff is exposed to the risk of losing State money and property whenever it files a patent suit in federal court. Without question, the Eleventh Amendment serves to bar all suits against an unconsenting State in a federal court. The Eleventh Amendment should also prevent a State patent owner from having to endure those similar risks in a foreign jurisdiction as the result of a post-filing transfer.

The prevalence of declaratory relief actions in patent disputes further illustrates the blurring of the plaintiff-defendant roles. To try to gain a favorable forum for an ongoing patent dispute, an accused infringer often will race to the courthouse and file a declaratory relief action on its home turf which is the mirror image of a threatened infringement action. *See* 8 Donald S. Chisum, *Chisum on Patents* § 21.02[4] (1997). The accused infringer hopes that by filing before the patentholder brings suit it will win the subsequent venue battle. Just as the Eleventh Amendment bars a declaratory relief infringement action against a State patent holder, *see, e.g., Genentech, Inc. v. Regents of the University of California*, 939 F. Supp. 639, 646 (S.D. Ind. 1996), the Amendment should preclude transfer of a case brought by a State patent holder to a venue in which the patent holder has not consented to suit. Otherwise the accused infringer could gain through a transfer motion what it could not accomplish through the early filing of a declaratory judgment action.[7]

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[7] The multidistrict litigation of which this case was a part presented this issue. In 1991, the district court in the Southern District of Indiana dismissed the University from Genentech's declaratory relief action, finding that the University as a sovereign was not subject to suit in Indiana. The Federal Circuit reversed in part, holding that Congress had subsequently abrogated UC's Eleventh Amendment rights in 1992 by enacting Public Law No. 102-560, 106 Stat. 4230, the Patent and Plant Variety Protection Remedy Clarification Act (codified at 35 U.S.C. §§ 271(h), 296). *See Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 940-42 (Fed. Cir. 1993). Following this Court's decision in *Seminole Tribe v. Florida*, 116 S. Ct. 1114 (1996), however, the Indiana district court held that the abrogation in the Act was unconstitutional under the Eleventh Amendment with respect to a declaratory judgment action brought against a State and again dismissed UC from Genentech's suit. *Genentech*, 939

Because the Regents had a sovereign right to choose their forum and because the substance of the action renders the State a defendant on significant issues, the involuntary transfer of venue implicates Eleventh Amendment and sovereignty concerns. That the text of the Amendment does not expressly refer to patent suits brought by a State plaintiff, to venue transfer, or to the multidistricting statute is not, as the Federal Circuit erroneously assumed, dispositive. As this Court explained in refuting contentions that the language of the Eleventh Amendment did not apply to a case before it:

> The text [of the Amendment] dealt in terms only with the problem presented by the decision in *Chisolm;* in light of the fact that the federal courts did not have federal question jurisdiction at the time the Amendment was passed (and would not have it until 1875), it seems unlikely that much thought was given to the prospect of federal question jurisdiction over the States.

*Seminole Tribe,* 116 S. Ct. at 1130. If federal question jurisdiction was not considered, certainly the drafters could not have contemplated the sovereignty implications associated with the federal courts' exclusive federal question jurisdiction over patent cases, let alone multidistrict legislation first enacted in 1968. Thus, the Amendment's text cannot be expected to provide explicit direction for the circumstances presented here. Rather, the principles underlying the Eleventh Amendment, as outlined by this Court, control.

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F. Supp. at 646. Genentech has appealed, and the Federal Circuit has not yet ruled.

### C. The State of California Did Not Consent to Transfer to the Indiana District Court by Filing Its Action in the Northern District of California.

The State agrees that it waived its sovereign immunity to a limited extent; at issue here is the scope of the waiver. The bedrock principle established by this Court is that a State's waiver of its sovereign privilege is limited to its terms. *Port Auth.*, 495 U.S. at 305-08; *Beers*, 61 U.S. at 529. When a State waives its sovereign immunity,

> [A]s this permission is altogether voluntary on the part of the sovereignty, it follows that it may prescribe the terms and conditions on which it consents to be sued, and the manner in which the suit shall be conducted, and may withdraw its consent whenever it may suppose that justice to the public requires it.

*Beers*, 61 U.S. at 529.

In *Port Authority*, the Court was explicit that a State may limit the scope of its waiver to a particular federal district court or venue. The question was whether New York and New Jersey waived their Eleventh Amendment immunity by consenting to venue in one federal district court. Both States had enacted statutes consenting generally to suits against the Port Authority. *Port Auth.*, 495 U.S. at 306. The relevant venue statute, however, provided that:

> [T]he foregoing consent . . . is granted on the condition that venue . . . shall be laid within a county or judicial district, established by one of said States or by the United States, and situated wholly or partially within the Port of New York District.

*Id.* at 307. Explaining that the venue statute limited the waiver to suit in the venues provided by the statute, the Court stated:

> [W]e believe that the provision directly indicates the extent of the States' waiver embodied in the consent provision. . . . The venue provision expressly refers to and qualifies the more general consent to suit provision.

*Id.* The Court stressed that:

> [I]ssues of venue are closely related to those concerning sovereign immunity, as this Court has indicated by emphasizing that "[a] State's constitutional interest in immunity encompasses not merely whether it may be sued, but where it may be sued."

*Id.* (quoting *Pennhurst*, 465 U.S. at 99). This Court also has emphasized that a waiver of a State's sovereign rights must be "unequivocal," *Pennhurst*, 465 U.S. at 99, and " 'by the most express language or by such overwhelming implication from the text as [will] leave no room for any other reasonable construction.' " *Atascadero*, 473 U.S. at 239-40 (quoting *Edelman v. Jordan*, 415 U.S. 651, 673 (1974)).

Based on this Court's clear precedents, the Regents urged the Federal Circuit to determine that the State of California's waiver of its Eleventh Amendment immunity was limited in scope to the venue in which it commenced this action. This Court requires a two-step analysis to decide whether a sovereign has waived immunity: (1) Did the State unambiguously consent to jurisdiction? (2) If so, what was the scope of the State's consent? *See Port Auth.*, 495 U.S. at 305-07; *Beers*, 61 U.S. at 529. The Federal Circuit completely disregarded the second step. Plainly, the act of initiating this suit in the Northern

District of California was consent to the jurisdiction of that district court. However, merely by bringing this action the Regents did not consent to trial in any other federal district court. Nor did the Regents subsequently consent to trial outside the Northern District of California.

Although federal district courts are empowered to transfer a case to another venue in which the case might have been brought, 28 U.S.C. § 1404(a), transfer is permitted "only when convenient and 'in the interest of justice.' " *Ferens v. John Deere Co.*, 494 U.S. 516, 532 (1990). Even where the plaintiff is not a sovereign, the plaintiff's choice of forum weighs heavily in its favor. *Robinson v. Giarmarco & Bill*, 74 F.3d 253, 260 (11th Cir. 1996); *Scheidt v. Klein*, 956 F.2d 963, 965 (10th Cir. 1992). When the plaintiff is a State, compelled to sue or forgo enforcing its patent rights, the State reasonably expects that, if venue lies in the district in which it filed suit, as a sovereign entity it will not have to subject itself to the indignity and burdens of litigating its claim for relief in a different and foreign jurisdiction to which it objects. At every opportunity, the Regents vigorously objected to the venue transfer in this case, and never consented to the transfer to the Southern District of Indiana.

## CONCLUSION

The State of California did not ever expressly nor implicitly consent to a trial in any venue other than the Northern District of California. The MDL panel was not empowered to transfer the case, and the Indiana district court was not empowered to transfer the case to itself for trial. The questions herein presented are ripe for this

Court's determination. Petitioner respectfully prays that this Court will grant *certiorari* in this case.

Dated: January 20, 1998

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## APPENDIX A

## UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

96-1175

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,

Plaintiff-Appellant,

v.

ELI LILLY AND COMPANY,

Defendant-Appellee.

*Harold J. McElhinny*, Morrison & Foerster LLP, of San Francisco, CA, argued for plaintiff-appellant. With him on the brief were *Donald S. Chisum*, *Alan K. Palmer*, *Rachel Krevans*, and *Debra A. Shetka*. Also with him on the brief were *Arthur I. Neustadt*, *Jean-Paul Lavalleye*, *Marc R. Labgold*, and *William J. Healey*, Oblon, Spivak, McClelland, Maier & Neustadt, P.C., of Arlington, VA. Of counsel was *Gladys H. Monroy*, Morrison & Foerster LLP, of San Francisco, CA.

*Charles E. Lipsey*, Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, argued for defendant-appellee. With him on the brief were *Donald R. Dunner*, *Howard W. Levine*, and *John R. Alison*. Of counsel on the brief was *Amy E. Hamilton*, Eli Lilly and Company, of Indianapolis, IN.

Appealed from: U.S. District Court for the Southern District of Indiana

Judge Dillin

**UNITED STATES COURT OF APPEALS**
**FOR THE FEDERAL CIRCUIT**

**96-1175**

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,

Plaintiff-Appellant,

v.

ELI LILLY AND COMPANY,

Defendant-Appellee.

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DECIDED: July 22, 1997

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Before NEWMAN, LOURIE, and BRYSON, *Circuit Judges*.

LOURIE, *Circuit Judge*.

The Regents of the University of California (UC) appeal from the judgment of the District Court for the Southern District of Indiana, holding that Eli Lilly & Company (Lilly) does not infringe U.S. Patent 4,652,525 or U.S. Patent 4,431,740 in its manufacture of human insulin; that the asserted claims of the '525 patent are invalid; and that both patents are unenforceable. *Regents of the Univ. of Cal. v. Eli Lilly and Co.*, 39 USPQ2d 1225 (S.D.Ind.1995). We hold that the district court (1) properly exercised jurisdiction over this case for trial on the merits, (2) did not err in concluding that the asserted claims of the '525 patent are invalid for failure to provide an adequate written description of the subject matter of the asserted claims, and (3) did not clearly err in finding that Lilly did not infringe the '740 patent. We further hold that the district court (4) abused its discretion in holding

that the '525 and '740 patents are unenforceable. We therefore affirm-in-part and reverse-in-part.

## BACKGROUND

In 1990, UC brought this action in the Northern District of California, alleging that Lilly was infringing claims 1, 2, and 4-7 of the '525 patent under the doctrine of equivalents and infringing claims 2-3, 5-6, 8-10, and 13-14 of the '740 patent, either literally or under the doctrine of equivalents. Lilly responded that it does not infringe any of the asserted claims, that the asserted claims are invalid, and that the patents are unenforceable. Lilly did not assert any counterclaims against UC.

The patents in suit relate to recombinant DNA technology[1] and, more specifically, to recombinant plasmids and microorganisms that produce human insulin, a protein involved in the regulation of sugar metabolism. A person unable to produce insulin is afflicted with diabetes. Prior to the development of recombinant techniques for the production of human insulin, diabetic patients were treated with injections of animal insulin, which often caused allergic reactions. Human insulin produced by recombinant methods is less likely to produce such reactions. It consists of two separate amino acid chains, a 21-amino acid A chain and a 30-amino acid B chain, which are linked only by disulfide bonds. Healthy

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[1] For a detailed discussion of recombinant DNA technology, see *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1207-08 n.4, 18 USPQ2d 1016, 1022 n.4 (Fed. Cir. 1991) and *In re O'Farrell*, 853 F.2d 894, 895-99, 7 USPQ2d 1673, 1674-77 (Fed. Cir. 1988) and references therein.

people produce insulin *in vivo* via the terminal enzymatic cleavage of preproinsulin (PPI) to yield proinsulin (PI), a single amino acid chain consisting of the A and B chains, linked by a sequence of additional amino acids that positions the A and B chains so that the disulfide bonds are readily formed. The PI is then further cleaved to liberate the linking sequence and yield insulin.

The '525 patent, the application for which was filed in May 1977, was based upon the determination of the PI and PPI cDNA sequences found in *rats*. Claim 1 of that patent reads as follows: "A recombinant *plasmid* replicable in procaryotic host containing within its nucleotide sequence a subsequence having the structure of the reverse transcript of an mRNA of a *vertebrate*, which mRNA encodes insulin." (emphasis added). Claim 2 relates to a recombinant procaryotic *microorganism* containing *vertebrate* insulin-encoding cDNA. Claims 4 and 5 depend from claim 2, and are limited, respectively, to *mammalian* and *human* insulin cDNA. Claim 6 depends from claim 1 and requires that the plasmid contain "at least one genetic determinant of the plasmid col E1." Claim 7 depends from claim 2 and requires that the microorganism be of a particular strain.

The '740 patent, the application for which was filed in September 1979, was based upon the determination of *human* PPI and PI cDNA sequences and the development of "tailoring" techniques for the incorporation of human PI cDNA into a recombinant plasmid. Using these techniques, a specific semi-synthetic DNA may be incorporated into a suitable transfer vector. Using one such tailoring technique, the human PI cDNA and the plasmid into which it is incorporated may be modified so that

they contain complimentary oligo-dC and oligo-dG ends, which facilitate the formation of the recombinant plasmid. Independent claim 2 of the '740 patent reads: "A DNA transfer vector *comprising* an inserted cDNA *consisting essentially of* a deoxynucleotide sequence coding for human proinsulin, the plus strand of said cDNA having a defined 5' end, said 5' end being the first deoxynucleotide of the sequence coding for said proinsulin." (emphasis added). Dependent claim 3 is directed, *inter alia*, to a recombinant microorganism containing the transfer vector of claim 2. Claim 5 reads: "A DNA transfer vector *comprising* a deoxynucleotide sequence coding for human proinsulin *consisting essentially of* a plus strand having the sequence: [nucleotides that encode human proinsulin, described in structural terms]." (emphasis added). Claim 6 depends from claim 5 in the same manner that claim 3 depends from claim 2: it is directed to a recombinant microorganism containing the transfer vector of claim 5. Claim 8 is directed to an example of a human PI-encoding recombinant plasmid described in the specification; and claims 9 and 10, to microorganisms containing that plasmid. Claims 13 and 14 are directed to a subset of the transfer vector genus of claim 5 and accordingly depend from claim 5.

Lilly makes human PI using a semi-synthetic DNA to yield a cleavable *fusion protein*[2] that consists of a bacterial protein, a "cleavable linkage" consisting of a single methionine residue, and human PI. After the fusion protein is

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[2] For a detailed discussion of fusion proteins, see *Schendel v. Curtis*, 83 F.3d 1399, 1400 & n.3, 38 USPQ2d 1743, 1744 & n.3 (Fed. Cir. 1996).

produced, the desired human PI is obtained by cleaving it from the remainder of the fusion protein.

In 1992, pursuant to 28 U.S.C. § 1407 (1994), the Judicial Panel on Multidistrict Litigation (JPML) consolidated this case with five other related cases for pre-trial proceedings in the District Court for the Southern District of Indiana. *In re Recombinant DNA Tech. Patent and Contract Litig.*, No. 912 (J.P.M.L. Feb. 19, 1992). UC petitioned this court for a writ of mandamus, seeking to vacate the transfer order as barred by the Eleventh Amendment and inconsistent with various prior decisions in the consolidated cases, including two decisions of the District Court for the Northern District of California in this case. *See In re Regents of the Univ. of Cal.*, 964 F.2d 1128, 1131-32, 22 USPQ2d 1748, 1751-52 (Fed. Cir. 1992). We denied UC's petition, holding that the transfer did not force unconsented suit upon UC and thus was permissible for purposes of pretrial discovery. *Id.*, at 1134, 22 USPQ2d at 1754.

In 1994, responding to Lilly's pretrial motion, the District Court for the Southern District of Indiana transferred venue to itself for trial on the merits pursuant to 28 U.S.C. § 1404(a) (1994). After conducting a bench trial, the court issued a memorandum opinion in which it ruled, *inter alia*, that (1) Lilly does not infringe the asserted claims of either patent, 39 USPQ2d at 1228-39, (2) the asserted claims of the '525 patent, those directed to mammalian, vertebrate, and human cDNA, are invalid for lack of an adequate written description, *id.* at 1239-41, and (3) both patents are unenforceable due to inequitable conduct on the part of UC, *id.* at 1247-58. UC appeals from

these rulings. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (1994).

## DISCUSSION

### A. Jurisdiction and Venue

As a preliminary matter, UC argues that the District Court for the Southern District of Indiana lacked jurisdiction to hear this case on the merits and was an inappropriate venue for trial. UC first argues that the Eleventh Amendment deprives the Indiana court of jurisdiction. Specifically, UC asserts that by choosing to bring suit in the District Court for the Northern District of California, it waived its Eleventh Amendment immunity only in California federal courts. Relying on *Port Authority Trans-Hudson Corp. v. Feeney*, 495 U.S. 299, 307 (1990), UC argues that the Eleventh Amendment bars the transfer of this case for trial on the merits. Lilly responds that the Eleventh Amendment is inapplicable where, as here, a state asserts a claim and no counterclaim against the state is involved. We agree with Lilly that the Eleventh Amendment does not preclude trial in Indiana.

The Eleventh Amendment provides that: "The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State." U.S. Const. amend. XI. The Supreme Court has recently confirmed that "the reference to actions 'against one of the United States' encompasses not only actions in which a State is named as a defendant, but also certain actions against state agents and state instrumentalities,"

such as UC. *Regents of the Univ. of Cal. v. Doe*, 117 S. Ct. 900, 903 (1997); *see also BV Eng'g v. Univ. of Cal.*, 858 F.2d 1394, 1395, 8 USPQ2d 1421, 1422 (9th Cir. 1988).

The question raised by this case is whether it is one that has been brought "against" UC. In deciding this question, we are aided by the Supreme Court's guidance in its opinion in *United States v. Peters*, 9 U.S. (5 Cranch) 115 (1809) (Marshall, C.J.). In that case, the Court declined to apply the Eleventh Amendment to bar a suit instituted against the heirs of a deceased state treasurer. The Court stated:

> The right of a state to assert, as plaintiff, any interest it may have in a subject, which forms the matter in controversy between individuals, in one of the courts of the United States, is not affected by [the Eleventh] amendment; nor can [the amendment] be so construed as to oust the court of its jurisdiction, should such claim be suggested. The amendment simply provides, that no suit shall be commenced or prosecuted against a state. The state cannot be made a defendant to a suit brought by an individual; but it remains the duty of the courts of the United States to decide all cases brought before them by citizens of one state against citizens of a different state, where a state is not necessarily a defendant.

*Id.* at 139. This case involves a state's assertion of a claim rather than a state being a defendant.

In the *Feeney* case relied on by UC, the Court applied the Eleventh Amendment because a claim for damages was asserted "against" a state instrumentality. The *Feeney* Court noted that "a State's Constitutional immunity

encompasses not merely *whether* it may be sued, but *where* it may be sued," 495 U.S. 299, 307 (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 99 (1984)), but the Court did not construe the Eleventh Amendment to apply to suits in which a state is solely a plaintiff, as UC is here. In fact, we do not believe that the Court has ever so construed the Eleventh Amendment. This is because the Eleventh Amendment applies to suits "against" a state, not suits by a state. Thus, we need not determine whether UC waived its immunity only in California, because this case does not create an Eleventh Amendment jurisdictional issue concerning which the question of waiver even arises. This case only involves UC's patent infringement claims and Lilly's defenses; it does not involve any claim or counterclaim *against* UC that places UC in the position of a defendant. Accordingly, we conclude that the Eleventh Amendment does not deprive the Indiana district court of jurisdiction in this case.

UC next argues that, under the law of the regional circuit to which appeal from the trial court would normally lie, the Indiana court abused its discretion by, as the court stated, transferring venue for trial on the merits from the California court to itself. *See Heller Fin., Inc. v. Midwhey Powder Co.*, 883 F.2d 1286, 1293 (7th Cir. 1987) (applying the abuse of discretion standard of review); *Lou v. Belzberg*, 834 F.2d 730, 739 (9th Cir. 1987) (same). Specifically, UC argues that the Indiana court abused its discretion by, *inter alia*, affording too much weight to the element of judicial economy in granting Lilly's motion to

transfer the case to Indiana.[3] Lilly responds that the court acted within its discretion by retaining the case for trial and that it properly considered and weighed the relevant factors before deciding to do so.

We agree with Lilly that the court did not err on this point. A federal district court may "[f]or the convenience of parties and witnesses, in the interest of justice, . . . transfer any civil action to any other district court or division where it might have been brought." 28 U.S.C. § 1404(a) (1994). The Indiana court based its decision to retain the case for trial on the merits on its finding that, although the convenience of the parties and witnesses did not favor either the Indiana or the California court, the interests of judicial economy would be served by trial in the Indiana court. Consideration of the interest of justice, which includes judicial economy, "may be determinative to a particular transfer motion, even if the convenience of the parties and witnesses might call for a different result." *Coffey v. Van Dorn Iron Works*, 796 F.2d 217, 220-21 (7th Cir. 1986); *Allen v. Scribner*, 812 F.2d 426, 436-37 (9th Cir. 1987) ("Because the transfer of this case undoubtedly would have led to delay, the district court did not abuse its discretion in denying Allen's motion notwithstanding possible inconvenience to the witnesses."); *Commodity Futures Trading Comm'n v. Savage*,

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[3] UC also argues that the Indiana court abused its discretion by erroneously determining that UC could have brought this suit in Indiana without the state of California's consent, by overruling inconsistent decisions of the California district court, and by failing to give special weight to UC's choice of forum. We have considered these arguments and do not find them to be persuasive.

611 F.2d 270, 279 (9th Cir. 1979) (affirming denial of transfer motion because "[t]he district court was familiar with the case and transfer may have led to delay"). Thus, the fact that the district court ultimately afforded little or no weight to the other factors does not, standing alone, indicate that the district court abused its discretion. On the contrary, in a case such as this in which several highly technical factual issues are presented and the other relevant factors are in equipoise, the interest of judicial economy may favor transfer to a court that has become familiar with the issues. Accordingly, the court did not abuse its discretion by transferring the case after affording determinative weight to the consideration of judicial economy.

In its reply brief, UC first raises another basis for determining that Indiana was an improper venue for trial. UC argues that 28 U.S.C § 1407(a) (1994) requires that a case transferred by the JPML for consolidated pretrial proceedings be returned for trial on the merits to the court from which it was transferred. Aware that it failed to address this issue in its opening brief in this appeal, UC contends that it adequately raised this argument when it filed its petition for mandamus seeking to vacate the transfer order for consolidation of discovery in Indiana. *See In re Regents*, 964 F.2d 1128, 22 USPQ2d 1748. Lilly first responds that UC waived this argument by failing to raise it in its opening brief in this appeal, regardless of the argument it made in its earlier petition. Lilly also maintains that the transfer was lawful, citing *In re American Continental Corp./Lincoln Savings & Loan Securities Litigation*, 102 F.3d 1524 (9th Cir. 1996), *cert. granted sub nom., Lexecon Inc. v. Milberg Weiss Bershad Hynes &*

*Lerach*, 65 U.S.L.W. 3761 (U.S. May 20, 1997) (No. 96-1482), for the proposition that § 1407(a) does not prohibit a discovery transferee court from transferring a case to itself for trial if an adequate reason for that transfer exists under 28 U.S.C. § 1404(a) (1994).

We agree with Lilly insofar as it argues that UC waived its argument regarding § 1407 by failing to raise it in its opening brief in this appeal. *See* Fed. R. App. P. 28(a)(6), 28(c); *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 800, 17 USPQ2d 1097, 1103 (Fed. Cir. 1990) ("[A]n issue not raised by an appellant in its opening brief . . . is waived."). UC's assertion that it adequately raised this argument when it filed its petition for mandamus is not persuasive. In denying that petition, we noted that UC expressed concern that, *inter alia*, "Lilly will maneuver to try the merits of the California actions in Indiana . . . thus defeating [UC's] expectation and entitlement that the merits of the California actions will be tried in California." *In re Regents*, 964 F.2d at 1133, 22 USPQ2d at 1753. However, we declined to address UC's concern then because "[t]hese possibilities can not be evaluated in the abstract." *Id.* An assertion that the district court had actually erred was required, not the mere assertion that UC feared a potential error. We thus told UC that if it desired to contest the Indiana court's self-transfer, it would be required to raise that issue if and when the Indiana court actually transferred the case to itself. Because UC failed to do so by asserting error in a writ of mandamus or in its opening brief in this appeal, we decline to address the merits of its argument. Having determined that the Indiana court had jurisdiction and that its transfer of venue to itself under § 1404 was not,

given the arguments properly before us, an abuse of that court's discretion, we address the remaining issues in UC's appeal.

B. The '525 Patent

1. Validity

The district court ruled that all of the claims of the '525 patent that UC asserted against Lilly, *viz.*, claims 1, 2, and 4-7, are invalid under § 112, ¶ 1, because the specification, although it provided an adequate written description of rat cDNA, did not provide an adequate written description of the cDNA required by the asserted claims. 39 USPQ2d at 1239-41.

Whether a specification complies with the written description requirement of § 112, ¶ 1, is a question of fact, which we review for clear error on appeal from a bench trial. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985). To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that

which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

We first consider claim 5, which is specific to a microorganism containing a human insulin cDNA. UC argues that the district court clearly erred in finding that claim 5 is invalid under § 112, ¶ 1. Specifically, UC argues that a constructive or prophetic example in the '525 specification describes in sufficient detail how to prepare the claimed organism. Lilly responds that the district court properly applied the written description requirement, as this court applied it in *Fiers*, 984 F.2d at 1170-71, 25 USPQ2d at 1605-06, and thus did not clearly err in finding that the cDNA encoding human insulin required by claim 5 is not adequately described in the '525 patent.

Claim 5 is directed to a recombinant procaryotic microorganism modified so that it contains "a nucleotide sequence having the structure of the reverse transcript of

an mRNA of a [human], which mRNA encodes insulin." Thus, the definition of the claimed microorganism is one that requires human insulin-encoding cDNA. The patent describes a method of obtaining this cDNA by means of a constructive example, Example 6. This example, however, provides only a general method for obtaining the human cDNA (it incorporates by reference the method used to obtain the rat cDNA) along with the amino acid sequences of human insulin A and B chains. Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5. The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

As indicated, Example 6 provides the amino acid sequence of the human insulin A and B chains, but that disclosure also fails to describe the cDNA. Recently, we held that a description which renders obvious a claimed

invention is not sufficient to satisfy the written description requirement of that invention. *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966. We had previously held that a claim to a specific DNA is not made obvious by mere knowledge of a desired protein sequence and methods for generating the DNA that encodes that protein. *See, e.g., In re Deuel*, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1215 (1995) ("A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein."); *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993). Thus, *a fortiori*, a description that does *not* render a claimed invention obvious does not sufficiently describe that invention for purposes of § 112, ¶ 1. Because the '525 specification provides only a general method of producing human insulin cDNA and a description of the human insulin A and B chain amino acid sequences that cDNA encodes, it does not provide a written description of human insulin cDNA. Accordingly, the district court did not err in concluding that claim 5 is invalid for failure to provide an adequate written description.

UC also argues that the district court erred in holding claims 1 and 2, which *generically* recite cDNA encoding vertebrate insulin, and claim 4, which is directed *generically* to cDNA encoding mammalian insulin, invalid. Dependent claims 6 and 7 similarly recite cDNA encoding vertebrate insulin. In support of this argument, UC cites the disclosure of a species (the rat insulin-encoding cDNA) within the scope of those generic claims. UC

argues, citing *In re Angstadt*, 537 F.2d 498, 190 USPQ 214 (CCPA 1976) and *Utter v. Hiraga*, 845 F.2d 993, 6 USPQ2d 1709 (Fed. Cir. 1988), that because the '525 specification meets the requirements of § 112, ¶ 1, for a species within both of these genera, the specification necessarily also describes these genera. Lilly responds that the district court did not clearly err in finding that cDNA encoding mammalian and vertebrate insulin were not adequately described in the '525 patent, because description of one species of a genus is not necessarily a description of the genus.

We agree with Lilly that the claims are invalid. Contrary to UC's argument, a description of rat insulin cDNA is not a description of the broad classes of vertebrate or mammalian insulin cDNA. A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials. *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . . ").

The cases UC cites in support of its argument do not lead to the result it seeks. These cases do not compel the conclusion that a description of a species always constitutes a description of a genus of which it is a part. These cases only establish that every species in a genus need

not be described in order that a genus meet the written description requirement. *See Utter*, 845 F.2d at 998-99, 6 USPQ2d at 1714 ("A specification may, within the meaning of § 112 ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses.") (affirming board's finding that an application that "describes in detail the geometry and components that make its *internal* pivot embodiment work" also sufficiently describes an interference count that is "silent as to the location of the pivot"). In addition, *Angstadt* is an enablement case and *Utter* involves machinery of limited scope bearing no relation to the complex biochemical claims before us.

In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the

genus because it is only an indication of what the gene does, rather than what it is. *See Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. *See Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.[4] This is analogous to enablement of a genus under

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[4] We note that in claims 4, 5, and 12-14 of the '740 patent, genera of DNA sequences encoding human PI or PPI are

§ 112, ¶ 1, by showing the enablement of a representative number of species within the genus. *See Angstadt*, 537 F.2d at 502-03, 190 USPQ at 218 (deciding that applicants "are *not* required to disclose *every* species encompassed by their claims even in an unpredictable art" and that the disclosure of forty working examples sufficiently described subject matter of claims directed to a generic process); *In re Robins*, 429 F.2d 452, 456-57, 166 USPQ 552, 555 (CCPA 1970) ("Mention of representative compounds encompassed by generic claim language clearly is not required by § 112 or any other provision of the statute. But, where no explicit description of a generic invention is to be found in the specification . . . mention of representative compounds may provide an implicit description upon which to base generic claim language."); *Cf. Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618 (determining that the disclosure of two chemical compounds within a subgenus did not describe that subgenus); *In re Grimme*, 274 F.2d 949, 952, 124 USPQ 499, 501 (CCPA 1960) ("[I]t has been consistently held that the naming of one member of such a group is not, in itself, a proper basis for a claim to the entire group. However, it may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by 'other appropriate language.' ") (citations omitted). We will not speculate in what other ways a broad genus of genetic material may be properly described, but it is clear to us, as it was to the district court, that the claimed genera of vertebrate and mammal cDNA are not described by the general language

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described by reference to the structure of the claimed DNA sequences rather than by reference to their function.

of the '525 patent's written description supported only by the specific nucleotide sequence of rat insulin.

Accordingly, we reject UC's argument that the district court clearly erred in finding claims 1, 2, 4, 6, and 7 invalid for failure to provide an adequate written description. Because we affirm the district court's ruling that all of the claims of the '525 patent asserted against Lilly are invalid, we need not consider whether Lilly infringed those claims. *See B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1583, 37 USPQ2d 1314, 1319 (Fed. Cir. 1996).

2. Enforceability

The district court also ruled the '525 patent unenforceable on the ground of inequitable conduct. The court based this ruling on its findings that UC had violated National Institutes of Health (NIH) guidelines in order to develop the patented invention as soon as possible and had falsified material in its patent application in an effort to disguise its violation. The court noted that at the time the application that became the '525 patent was filed, NIH had certified only three plasmids for use with mammalian DNA: pSC101, pCR1, and pMB9. 39 USPQ2d at 1249. It then found that UC researchers knowingly used the uncertified pBR322 plasmid to hasten their determination of the rat PI and PPI cDNA sequences, and misrepresented that they had used pMB9, a certified plasmid, in the actual examples of their patent application. The court also found that a reasonable patent examiner would have viewed this misrepresentation as material to patentability. *Id.* at 1254.

UC argues that we should reverse the district court's ruling because it is based on a misinterpretation of the applicable law on inequitable conduct. Specifically, UC argues that the district court improperly considered alleged misrepresentations made to the NIH and Congress, and failed to properly consider whether the alleged misrepresentation in the patent application regarding the use of pMB9 was material to patentability. UC also argues that the district court clearly erred in finding that UC actually used pBR322 and then misrepresented that it used pMB9. In response, Lilly argues that under *General Electro Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 30 USPQ2d 1149 (Fed. Cir. 1994), UC's misrepresentation was sufficient to support a finding of inequitable conduct, and that such a misrepresentation need not bear directly on patentability as long as that misrepresentation was made in an effort to obtain a patent more quickly than otherwise. Lilly also argues that the district court properly found that UC's alleged pattern of deceit before a variety of governmental bodies was sufficient to render the patent unenforceable under the broad doctrine of "unclean hands." *See, e.g., Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 19 USPQ 228 (1933).

"A determination of inequitable conduct is committed to a district court's discretion. Accordingly, we review the district court's judgment for an abuse of discretion." *Kolmes v. World Fibers Corp.*, 107 F.3d 1534, 1541, 41 USPQ2d 1829, 1834 (Fed. Cir. 1997) (citing *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876, 9 USPQ2d 1384, 1392 (Fed. Cir. 1988)). To overturn a discretionary ruling of a district court, "the appellant must establish that the ruling is based on clearly erroneous

findings of fact or on a misapplication or misinterpretation of applicable law, or evidences a clear error of judgment on the part of the district court." *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178, 33 USPQ2d 1823, 1827 (Fed. Cir. 1995).

We conclude that the district court abused its discretion in holding the '525 patent to be unenforceable. An infringer asserting an inequitable conduct defense must demonstrate by clear and convincing evidence that the applicant or his attorney either failed to disclose material information or submitted false material information to the Patent and Trademark Office (PTO) and that the applicant or his attorney did so with an intent to deceive the PTO. *See Kingsdown*, 863 F.2d at 872, 9 USPQ2d at 1389. Information is material if a reasonable examiner would have considered it important to the patentability of a claim. *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1559, 223 USPQ 1089, 1092 (Fed. Cir. 1984).

The alleged misinformation submitted to the PTO in this case consists of statements in Examples 4 and 5 of the specification that the pMB9 plasmid was used as the cloning vector for the rat cDNA when pBR322 appears to have been used. Lilly does not argue that the pMB9 plasmid was inoperable in the stated examples, only that Examples 4 and 5 should not have been stated as actual examples (even though they presumably could have been stated as constructive, *i.e.*, hypothetical, examples). Accordingly, Lilly must demonstrate that this distinction would have been considered material by a reasonable patent examiner. We conclude that it has not done so by clear and convincing evidence.

There is no reason to believe that a reasonable examiner would have made any different decision if UC had framed Examples 4 and 5 as constructive examples. *See Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1578, 224 USPQ 409, 415 (Fed. Cir. 1984) ("Even if intent could be inferred, and if the examples were constructive but not disclosed to the examiner as such, [the alleged infringer] has not shown the nondisclosure to have been material, *i.e.*, important to an examiner in allowing the patent to issue."); Manual of Patenting Examining Procedure (MPEP) § 707.07(l) (5th ed. 1993) ("The results of the tests and examples should not normally be questioned by the examiner unless there is a reasonable basis for questioning the results."); *cf. Consolidated Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 808-09, 15 USPQ2d 1481, 1484 (Fed. Cir. 1990) (affirming a finding of inequitable conduct based on an applicant's intentional disclosure of a "fictitious, inoperable" example and withholding of a best mode.). Moreover, the examiner would not have made any different decision if pBR322, the plasmid the district court found was actually used, was recited in the examples, because, as the record shows, the procedures described in Examples 4 and 5 for rat insulin cDNA worked to yield the intended results irrespective of whether pMB9 or pBR322 was used. The misidentification of the plasmid was therefore not material to patentability. Thus, no inequitable conduct occurred in the procurement of the patent.

In addition, contrary to the findings of the district court, a reasonable patent examiner would not have considered non-compliance with the NIH guidelines to be

material to patentability. The district court based its finding of materiality on the theory that if the applicant had complied with the guidelines, the application might have been delayed and the applicants might not have been the first to apply for a patent on the claimed subject matter. However, such unfounded speculation is not clear and convincing evidence of materiality.

*General Electro Music* does not support Lilly's argument that UC's failure to have actually used pMB9 would have been material to patentability. In *General Electro Music*, we concluded that "a false statement in a petition to make special is material if, as here, it succeeds in prompting expedited consideration of the patent." 19 F.3d at 1411, 30 USPQ2d at 1154. We so concluded because, by filing a petition to make special, the applicant "requested special treatment and induced reliance on its statement that a prior art search had been conducted." *Id.* As explained above, UC's alleged mischaracterization of the pMB9 work as an actual example did not induce the examiner to act, or not to act, in reliance thereon. UC got no advantage in the patent examining process. Therefore, we conclude that the district court clearly erred in finding that the misidentification of the plasmid was material to patentability.

We also reject Lilly's alternative argument that the patent is unenforceable under the doctrine of "unclean hands." This court has previously refused to afford equitable relief in that guise in the absence of proof of materiality. In *J.P. Stevens*, 747 F.2d at 1560 n.7, 223 USPQ2d at 1093 n.7, we rejected the argument that "unclean hands" could render a patent unenforceable without proof of materiality because such a "categorization is inconsistent

with this court's view that materiality is a necessary ingredient of any inequitable conduct." Accordingly, there is no legal basis for the conclusion that inequitable conduct occurred in the procurement of the patent and the district court therefore abused its discretion in its conclusion that the patent was unenforceable.

C. The '740 Patent

1. Infringement

The district court ruled that Lilly did not infringe claims 5-6 and 8-10 of the '740 patent either literally or under the doctrine of equivalents, 39 USPQ2d at 1231-38, and did not infringe claims 2-3 and 13-14 of the '740 patent under the doctrine of equivalents, *id.* at 1238. After evaluating the specification and the prosecution history, and receiving extrinsic evidence, the court construed these claims to be limited to genetic constructs (*i.e.*, "plasmids" and "transfer vectors") and microorganisms from which human PI is directly expressed. Accordingly, the court found that Lilly, which does not make or use such constructs or microorganisms, but expresses a recombinant fusion protein that is later cleaved to yield human PI, did not literally infringe the asserted claims. The court further determined that Lilly did not infringe the claims under the doctrine of equivalents because claim amendments made during the prosecution of the patent application bar UC from successfully asserting that the materials Lilly uses for expressing a recombinant fusion protein are equivalent to the claims of the '740 patent.

Challenging the district court's finding of a lack of literal infringement, UC argues that the district court

incorrectly interpreted the claims. Specifically, UC argues that the use of the term "comprising" in the claims indicates that a transfer vector such as that used by Lilly will infringe the claims as long as it includes the inserted cDNA encoding human PI, irrespective of the presence of other elements such as the DNA encoding the remainder of Lilly's fusion protein. Lilly responds that the district court correctly interpreted the claims in light of the prosecution history. Lilly argues that a prior art rejection was based on the examiner's conclusion that the prior art taught how to make recombinant insulin as part of a fusion protein and that UC therefore obtained allowance of the claims by specifically disclaiming transfer vectors that encode fusion proteins.

A determination of infringement requires a two-step analysis. "First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process." *Carroll Touch, Inc. v. Electro Mechanical Sys., Inc.*, 15 F.3d 1573, 1576, 27 USPQ2d 1836, 1839 (Fed. Cir. 1993). The first step, claim construction, is a question of law which we review *de novo;* the proper construction of the claims is based upon the claim language, the specification, the prosecution history, and if necessary to aid the court's understanding of the patent, extrinsic evidence. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-81, 34 USPQ2d 1321, 1329-31 (Fed. Cir. 1995) (in banc), *aff'd*, 116 S.Ct. 1384, 38 USPQ2d 1461 (1996). The second step, determining whether a particular device infringes a properly construed claim, is a question of fact which we review for clear error on appeal from a bench trial. *See* Fed. R. Civ. P. 52(a); *Fromson v. Advance Offset*

*Plate, Inc.*, 720 F.2d 1565, 1569, 219 USPQ 1137, 1140 (Fed. Cir. 1983). In order to prove infringement, a patentee must show that "the accused device includes every limitation of the [asserted] claim or an equivalent of each limitation." *Dolly, Inc. v. Spalding & Evenflo Cos.*, 16 F.3d 394, 397, 29 USPQ2d 1767, 1769 (Fed. Cir. 1994).

We agree with Lilly that UC surrendered coverage of DNA that encodes a fusion protein. The district court correctly interpreted the asserted claims to be limited to genetic constructs and microorganisms that do not include DNA coding for a fusion protein. UC argues that the direct expression of human PI and the expression of human PI via a fusion protein are both described in the patent as part of the invention of the '740 patent, but that fact doesn't change the prosecution history which indicates that UC surrendered coverage of the latter in order to overcome prior art.

This surrender is best exemplified by the prosecution history relating to the claims that ultimately issued as claims 2 and 5. These claims as originally filed were directed, with varying degrees of specificity, to a DNA transfer vector *comprising* a DNA sequence coding for human PI. The word "comprising," as UC argues and as is well-established, permits inclusion of other moieties. However, during the prosecution of the patent, the examiner rejected these claims as unpatentable based on, *inter alia*, Ullrich *et al.*, 196 Science 1313 (June 17, 1977) and Villa-Komaroff *et al.*, 75 PNAS 3727 (August 1978).[5] The

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[5] Several other publications of record before the PTO were found by the district court to teach the use of fusion proteins in

district court, essentially repeating the statements made by the patent examiner during the prosecution of the patent, found that these references taught,[6] respectively, the need "to combine the genetic information for the eukaryotic insulin gene with prokaryotic regulatory sequences, to obtain expression of insulin in bacteria," and "a general method for the expression and secretion of any eukaryotic protein [such as human PI] provided another protein . . . will serve as a carrier [as part of a fusion protein], by virtue of its leader sequence." 39 USPQ2d at 1232. The examiner thus rejected the claims because he believed that the prior art taught the use of recombinant eukaryotic/procaryotic fusion proteins for the production of a eukaryotic protein, including insulin, in a recombinant bacterium.

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the production of human PI. *See* 39 USPQ2d at 1231 n.12. For the sake of brevity, we do not discuss them here.

[6] UC also appears to argue that the district court clearly erred in finding that these references taught the production of human PI via a fusion protein. This argument misses the point of the analysis of prosecution history. As the Supreme Court recently noted, the question of the correctness of the examiner's rejection is "properly addressed on direct appeal from the denial of the patent, and will not be revisited in an infringement action." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 117 S.Ct. 1040, 1051 n.7, 137 L.Ed.2d 146, 41 USPQ2d 1865, 1872-73 n.7 (1997). In construing the claims in view of prosecution history or in deciding whether to estop a patentee from asserting a certain range of equivalents, a court may only explore "the reason (right or wrong) for the objection and the manner in which the amendment addressed and avoided the objection." *Id.* Thus, the district court properly accepted the examiner's arguments for the purpose of construing the claims in view of the prosecution history.

In an effort to overcome the rejection based on these references, UC first amended claim 2 to read, in pertinent part: "A DNA transfer vector comprising an inserted cDNA *having* a[DNA] sequence coding for human [PI]. . . . " The word "having" still permitted inclusion of other moieties. When again confronted by a rejection based upon the same references and a later requirement that the word "having" be changed to "consisting essentially of," a narrower term, UC ultimately complied by amending claim 2 to its present form, *viz.*, "A DNA transfer vector comprising an inserted cDNA *consisting essentially of* a[DNA] sequence coding for human [PI]." Similarly, UC amended claim 5 to its present form, which reads, in pertinent part: "A DNA transfer vector comprising a[DNA] sequence coding for human [PI] *consisting essentially of* a plus strand having the sequence. . . . " (emphasis added). The examiner allowed these claims, noting that the required "consisting essentially of" language "excludes from the cDNA the presence of sequences other than [those coding for PI]." We agree with the district court that UC thus narrowed its claims in response to a prior art rejection to exclude the materials producing a fusion protein, as Lilly now does. UC urges us to read the examiner's statement on allowance of the claims narrowly as pertaining only to claim 2 and to exclude only DNA other than naturally-occurring human cDNA. However, that statement is not so limited; it expressly applies to claim 5 and, moreover, reflects the examiner's consistent requirement, acquiesced in by UC,

that the DNA inserted in the claimed vectors code only for PI, not for a PI-containing fusion protein.[7]

We have considered all of the other arguments made by UC, including its assertion that the examiner's rejections were based on a distinction between tailored and non-tailored cDNA, but find them to be unpersuasive. In light of the prosecution history, we agree with the district court that claims 5 and 6, which contain the language added during prosecution, cannot be construed to literally cover Lilly's expression of human PI via a fusion protein. Furthermore, UC has stated in its appeal brief that, for purposes of the analysis of literal infringement, the scope of claims 8-10 is no broader than that of claims 5 and 6, and that it does not appeal the court's finding with respect to claims 8-10. Accordingly, we affirm the district court's construction of claims 5-6 and 8-10; its factual finding that Lilly does not literally infringe claims 5-6 is not clearly erroneous and is therefore also affirmed.

Regarding the district court's application of the doctrine of equivalents, UC argues that the district court improperly interpreted the prosecution history to indicate that UC had disclaimed vectors encoding fusion proteins instead of to indicate, as properly interpreted, that the claims were limited to "tailored" cDNA inserts. However, as indicated above, we find no error in the

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[7] UC's later-filed amendment pursuant to 37 C.F.R. § 1.312 (1983) ("Amendments after allowance"), in which it argued that the claims as allowed would not necessarily encompass the "trivial" oligo-dC and oligo-dG ends actually used to construct the plasmid of the '740 patent, also supports this broader reading of the examiner's statement.

district court's interpretation of the claims and the prosecution history and hence its conclusion that Lilly does not infringe the asserted claims under the doctrine of equivalents.

When a claim has been narrowed by amendment for a "substantial reason related to patentability," such as to avoid a prior art rejection, the patentee may not assert that the surrendered subject matter is within the range of equivalents. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 117 S.Ct. 1040, 1049-51, 41 USPQ2d 1865, 1871-73 (1997); *Insituform Techs., Inc. v. Cat Contracting, Inc.*, 99 F.3d 1098, 1107, 40 USPQ2d 1602, 1609 (Fed. Cir. 1996), *cert. denied*, 117 S.Ct. 1555 (1997); ("Prosecution history estoppel bars the patentee from recapturing subject matter that was surrendered by the patentee during prosecution in order to promote allowance of the claims."). "The application of prosecution history estoppel is a question of law subject to *de novo* review." *Id.; see also Warner-Jenkinson*, 117 S.Ct. at 1049-51, 41 USPQ2d at 1871-73.

As the district court properly concluded, the above-described prosecution history estops UC's '740 patent from dominating Lilly's expression of its fusion protein. As a matter of law, the material used by Lilly for expressing its fusion protein is not equivalent to that of the above-analyzed claims, or to the materials of the other asserted claims, *i.e.*, claims 2-3 and 13-14, for such an application of the doctrine of equivalents would allow UC to recapture subject matter it surrendered during the prosecution of the '740 patent. Accordingly, UC cannot meet its burden of establishing infringement under the doctrine of equivalents. The district court did not clearly err in determining that Lilly did not infringe the '740

patent, either literally or under the doctrine of equivalents.

2. Enforceability

The district court ruled that the '740 patent was unenforceable for inequitable conduct. 39 USPQ2d at 1255-58. The court based this ruling in part on its finding that UC failed to disclose to the PTO a highly-material reference, European Patent Application No. 1929 (EPA-1929), entitled "Plasmid for Transforming Bacterial Host to Render It Capable of Polypeptide Expression" in which the expression of human somatostatin and insulin are used as examples.[8] The court also based its ruling on its finding that UC was made aware of the materiality of EPA-1929 when it was cited as prior art by the European Patent Office (EPO) during the prosecution of the European counterpart of the application that led to the '740 patent. The court found that under these facts, it would "draw an inference of intent to mislead," *id.* at 1257, and accordingly, found that UC had engaged in inequitable conduct.

UC argues that it did not have a duty to disclose EPA-1929 to the PTO because it was merely cumulative of the references it had submitted to the PTO. Specifically, UC argues that EPA-1929 was cumulative of the two references on which EPA-1929 was based, which were already before the examiner when UC became aware of EPA-1929: Goeddel *et al.*, 76 PNAS 3727 (1979) and

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[8] This application was filed by Genentech, Inc. and named Drs. Itakura and Riggs as inventors.

Itakura *et al.*, 198 Science 1056 (1977).[9] UC also argues that the district court misapplied the law on inequitable conduct by inferring an intent to deceive when the uncited reference was merely cumulative. Lilly responds that EPA-1929 was not cumulative because, unlike the reference before the examiner, it described a specific, enabling technique for making "tailored" DNA that would encode for a fusion protein including human PI. Lilly argues that UC's assertions of subjective good faith amount to no more than a mere denial of bad faith and accordingly that the district court properly disregarded those assertions. We agree with UC that the district court clearly erred in finding that EPA-1929 was not cumulative and, accordingly, in inferring an intent to deceive.

As stated above, we review a district court's ruling that a patent is unenforceable for inequitable conduct under an abuse of discretion standard. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876, 9 USPQ2d 1384, 1392 (Fed. Cir. 1988). An infringer asserting an inequitable conduct defense must prove by clear and convincing evidence that the applicant or his attorney failed to disclose material information or submitted false material information to the PTO, with an intent to deceive the PTO. *See id.* at 872, 9 USPQ2d at 1389. Information is material if a reasonable examiner would have considered it important to the patentability of a claim. *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1559, 223 USPQ 1089, 1092 (Fed. Cir. 1984). However, even where an applicant fails to disclose an otherwise material prior

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[9] Drs. Itakura and Riggs, inventors of the EPA-1929 subject matter, are noted as authors on both of these articles.

art reference, that failure will not support a finding of inequitable conduct if the reference is "simply cumulative to other references," *i.e.*, if the reference teaches no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO. *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582, 18 USPQ2d 1001, 1014 (Fed. Cir. 1991).

The district court correctly found that UC knew of the materiality of EPA-1929 because the EPO considered EPA-1929 to be material to the examination of the European counterpart of the '740 patent. However, if EPA-1929 was merely cumulative of other references already before the examiner, UC's failure to cite it will not support a finding of inequitable conduct because one is justified in not submitting cumulative prior art. The record indicates that EPA-1929 was cumulative. The examiner had already noted the relevance of both the Itakura article, entitled "Expression in *Escherichia coli* of Chemically Synthesized Gene for the Hormone Somatostatin," and the Goeddel article, entitled "Expression in *Escherichia coli* of Chemically Synthesized Genes for Human Insulin." As is suggested by their respective titles and their dates of publication and submission, the work described in the two articles is essentially the same as that described in EPA-1929. In fact, the record indicates that the European patent examiner cited EPA-1929 against the European counterpart of the '740 patent, but cited the Goeddel article merely to demonstrate the state of the art and did not cite the Itakura article at all.

Lilly argues that these articles are distinguishable from EPA-1929 based on the fact that EPA-1929 also includes a claim (claim 6) directed, in part, to a plasmid

encoding human proinsulin. But the inclusion of a claim is not controlling in a determination whether EPA-1929 is cumulative. What is relevant is whether EPA-1929 discloses subject matter relevant to the examination of the '740 patent application that is not taught by the Goeddel and Itakura articles. Plainly it does not. The Goeddel article and EPA-1929 *describe* in similar detail the same experiments which led to the production of a recombinant human insulin/ß-galactosidase fusion protein. That Genentech attempted to claim a plasmid encoding human proinsulin in EPA-1929 does not add to its disclosure compared with the Goeddel article. We therefore conclude that the district court clearly erred in finding that EPA-1929 was not cumulative.

Because we conclude that the district court's finding of materiality was clearly erroneous, we also necessarily conclude that the district court clearly erred in inferring deceptive intent from the mere fact that UC did not cite EPA-1929. UC's failure to disclose the EPA-1929 reference, given its cumulative nature, is not clear and convincing evidence of inequitable conduct. Because the district court's conclusion that the '740 patent is unenforceable for inequitable conduct is based on clearly erroneous findings of materiality and intent, that conclusion is reversed.

## CONCLUSION

The district court properly exercised jurisdiction over this case and did not abuse its discretion in transferring the case to itself for a trial on the merits. It did not clearly err in finding that the '525 patent does not provide an

adequate written description of the subject matter of the asserted claims and thus properly held that those claims are invalid, nor did it clearly err in finding that Lilly did not infringe the asserted claims of the '740 patent. The court abused its discretion in holding that the '525 and '740 patents are unenforceable. Accordingly, the decision of the district court is

AFFIRMED-IN-PART and REVERSED-IN-PART.

COSTS

Costs to Lilly.

## APPENDIX B

**In re the REGENTS of the UNIVERSITY OF CALIFORNIA, Petitioner,**

**Misc. No. 330.**

United States Court of Appeals,
Federal Circuit.

May 18, 1992.

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Gerald P. Dodson of Townsend & Townsend, Thomas D. Nevins of Broad, Schulz, Larson & Wineberg, San Francisco, Cal., for petitioner.

Donald R. Dunner of Finnegan, Henderson, Farabow, Garrett & Dunner, Washington, D.C., for respondent, Eli Lilly & Co. Of counsel were Charles E. Lipsey and Susan Haberman Griffen.

Salem M. Katsh of Weil Gotshal & Manges, New York, N.Y., for respondent, Genetech, Inc. Of counsel were Ira M. Millstein, Howard B. Comet, David K. Barr, and Christina Del Valle.

Before NEWMAN, Circuit Judge, SKELTON, Senior Circuit Judge, and LOURIE, Circuit Judge.

PAULINE NEWMAN, Circuit Judge.

The Regents of the University of California petition for extraordinary writ, ordering the Judicial Panel on Multidistrict Litigation to vacate its order consolidating

five pending lawsuits for coordinated pretrial proceedings in the Southern District of Indiana.[1] The petition is opposed by Genentech, Inc. and Eli Lilly and Co. Alternatively, the Regents request that the coordinated pretrial proceedings be conducted in the Northern District of California; Genentech supports this request, and Lilly opposes it.

I

Genentech and Lilly challenge the Federal Circuit's jurisdiction to entertain this mandamus petition, and request dismissal or transfer to the Seventh Circuit Court of Appeals. Genentech and Lilly state that this court does not have jurisdiction under 28 U.S.C. § 1651[2] to review transfer orders generally; and that even if jurisdiction were to exist under § 1651, review of Multidistrict Panel transfer orders is limited by 28 U.S.C. § 1407(e)[3] to the geographic circuit courts of appeal.

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[1] *In re Recombinant DNA Technology Patent and Contract Litigation*, Docket No. 912 (J.P.M.L. February 19, 1992).

[2] **28 U.S.C. § 1651 Writs**

(a) The Supreme Court and all courts established by Act of Congress may issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law.

[3] **28 U.S.C. § 1407 Multidistrict litigation**

(e) No proceedings for review of any order of the panel may be permitted except by extraordinary writ pursuant to the provisions of title 28, section 1651, United States Code. . . . Petitions for an extraordinary writ to review an order to transfer . . . shall be filed only in the court of appeals having jurisdiction over the transferee district.

The Federal Circuit's authority in extraordinary writ is beyond challenge. When a petition is brought in connection with a case in the Federal Circuit's appellate jurisdiction, this court has conscientiously administered its responsibility. *E.g., In re Newman*, 782 F.2d 971, 973, 228 USPQ 450, 452 (Fed. Cir. 1986) ("Because this court, and only this court, has jurisdiction over any appeal from a final decision in this case, it has jurisdiction to hear and decide this [mandamus] petition.") The Federal Circuit has considered questions of venue when properly raised. *E.g., Exxon Chemical Patents, Inc. v. The Lubrizol Corp.*, 935 F.2d 1263, 19 USPQ2d 1061 (Fed. Cir. 1991); *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574, 16 USPQ2d 1614 (Fed. Cir. 1990), *cert. denied*, ___ U.S. ___, 111 S.Ct. 1315, 113 L.Ed.2d 248 (1991); *Kahn v. General Motors Corp.*, 889 F.2d 1078, 12 USPQ2d 1997 (Fed. Cir. 1989). Such issues, properly before the Federal Circuit on appeal, are no less within our jurisdiction when raised by extraordinary writ, *e.g., In re Cordis Corp.*, 769 F.2d 733, 226 USPQ 784 (Fed. Cir. 1985).

Genentech and Lilly assert that whether or not the Federal Circuit may exercise jurisdiction under § 1651, it does not have "jurisdiction over the transferee district", quoting § 1407(e), a statutory prescription that Genentech and Lilly say applies only to the geographic circuit courts. This misconstrues the statute, for the distinction drawn in § 1407(e) is between the transferee and the transferor district. With the formation of the Federal Circuit and its statutory assignment as exclusive appellate tribunal in patent cases, see 28 U.S.C. § 1295, this court acquired the authority of § 1651 and the responsibility of

§ 1407(e). The text of § 1407(e), enacted in 1968, readily accommodates the establishment of this court in 1982.

Lilly cites *Wood v. United States*, 961 F.2d 195 (Fed. Cir. 1992) in support of its position. The citation is inapt. The court in *Wood* discussed two transfers: (1) the transfer of a Federal Tort Claims Act case from the Northern District of California to the Southern District of Florida; the Federal Circuit held that it was without jurisdiction to review this transfer, since a final judgment in an action under the Federal Tort Claims Act is not appealable to the Federal Circuit; and (2) the subsequent transfer of the case from the Southern District of Florida to the Claims Court on the basis that it did not sound in tort, but was based upon a contract and jurisdiction lay only under the Tucker Act; this transfer was reviewed by the Federal Circuit under 28 U.S.C. § 1292(d)(4)(A). The jurisdiction conferred by § 1292(d)(4)(A) was held not to authorize review of the prior transfer from California to Florida, for at the time of that transfer jurisdiction was based solely on the Federal Tort Claims Act. *Wood* does not hold that only the geographic courts of appeal can review transfer orders in cases over which this court has exclusive appellate jurisdiction. Indeed, *Wood* supports the contrary position.

The Federal Circuit's jurisdiction over this petition is in accordance with 28 U.S.C. §§ 1295, 1407, and 1651. The request to dismiss or transfer the petition for lack of jurisdiction is DENIED.

II

These five lawsuits arose out of various research arrangements involving the Regents, Genentech, and Lilly, and relate to recombinant DNA technology and its use in the production of human insulin and human growth hormone (hGH).

Two suits are pending in the Northern District of California:

(1) *Regents v. Genentech and Lilly,* No. C90-2232. The Regents allege that Genentech's production of recombinant DNA hGH products infringes the university's '877 patent entitled "Recombinant DNA Transfer Vectors". Genentech had added Lilly, the exclusive licensee under the '877 patent, to this action.

(2) *Regents v. Lilly,* No. C90-0373. The Regents allege that Lilly's production of recombinant DNA human insulin products infringes certain patents owned by the university.

Three suits are pending in the Southern District of Indiana:

(3) *Lilly v. Genentech,* No. 87-219-C. Lilly seeks a declaratory judgment that four patents owned by Genentech are either invalid or not infringed by Lilly's production of recombinant DNA hGH products. Genentech has counterclaimed for infringement of thirteen patents.

(4) *Genentech v. Lilly,* No. 88-1463-C. Genentech charges Lilly with breach of contract, misappropriation of trade secrets, and related wrongs, based on Lilly's alleged use, in production of hGH, of technology licensed solely for use in production of insulin. Lilly's offset claims are

based on agreements between Lilly and the Regents in which Lilly funded research at the university. Issues arise from the movement of scientists from the university to Genentech, bringing with them Lilly-funded materials.

(5) *Genentech v. Lilly and Regents*, No. 90-1679-C. Genentech seeks a declaration that the Regents' '877 patent is invalid, unenforceable, or not infringed by Genentech's production of recombinant DNA hGH products. Genentech also charges the Regents and Lilly with antitrust and state law violations.

Genentech moved the Panel on Multidistrict Litigation to establish coordinated pretrial proceedings in these five actions in the Northern District of California. After briefing and argument the Panel granted Genentech's request for coordination, but ordered that the coordinated proceedings be conducted by the court in the Southern District of Indiana. This petition ensued.

28 U.S.C. § 1407(a) authorizes the Panel on Multidistrict Litigation to transfer to any district court, for coordinated or consolidated pretrial proceedings, civil actions pending in more than one district and involving one or more common questions of fact. The Panel must determine that coordinated pretrial proceedings "will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions." 28 U.S.C § 1407(a). The purpose of this statute is the avoidance of conflicting and duplicative pretrial demands on parties and witnesses in related cases. *See* H.R.Rep. No. 1130, 90th Cong., 2nd Sess. (1968), *reprinted in* 1968 U.S.C.C.A.N. 1898, 1899-1900; *In re Plumbing Fixture Cases*, 298 F. Supp. 484, 490-92 (J.P.M.L.1968). The Regents

do not dispute the legitimacy of this purpose, but argue that in this case the transfer is unauthorized, improper, and inefficient.

The Regents state that since the Indiana and California district courts have already considered and decided transfer and venue questions in these cases, their decisions are the law of the case and can not be overruled by the Multidistrict Panel. The Regents argue that the Multidistrict Panel's order is contrary to five district court decisions, and that the Panel abused its discretion in failing to defer to these decisions as the law of the case.

We need not consider the broader aspects of applicability of the doctrine of law of the case in multidistrict litigation, *see In re Multi-Piece Rim Products Liability Litigation*, 653 F.2d 671, 678 (D.C. Cir. 1981), for review of the five decisions to which the Regents refer shows that none of the decisions treated the question that was before the Multidistrict Panel. Following is a summary of these decisions:

(1) The decision of Judge McKinney of the Southern District of Indiana in No. 90-1679-C, dismissing the Regents from *Genentech v. Lilly and Regents*.

The declaratory judgment action filed by Genentech in Indiana was dismissed in view of the infringement action filed in California one day later by the Regents. Dismissal was based both on discretionary grounds and reliance on the Eleventh Amendment. This dismissal was appealed to the Federal Circuit, and is *sub judice*.

The Regents characterize this decision as holding that the Northern District of California is the correct venue for

determination of the infringement issue. We do not share this characterization, for this decision did not address the issue of choice of venue. The court simply declined to exercise jurisdiction over a declaratory judgment action brought under these circumstances. The court also relied, as an alternative ground, on the Eleventh Amendment.

The Indiana court did not consider the larger picture raised by the existence of five actions, that is, whether pretrial coordination among all of the actions might achieve desirable economies and efficiencies.

(2) The decision of Judge Dillin of the Southern District of Indiana in No. 90-171-C, dismissing the declaratory judgment action brought by Lilly against the Regents.

This declaratory judgment action was also dismissed in favor of the infringement action filed in California by the Regents against Lilly. As in case (1), there was no discussion of issues relating to pretrial coordination. Insofar as the record shows, the issues under § 1407(a) that were before the Multidistrict Panel were not decided in the Southern District of Indiana, either explicitly or implicitly.

No theory of law of the case or other estoppel against the Multidistrict Panel has been shown to be supported by these Indiana decisions.

(3) The decision of Judge Weigel of the Northern District of California, No. C90-0373, denying Lilly's motion to dismiss or transfer *Regents v. Lilly* to Indiana.

Lilly had challenged venue in California on the basis of *Fourco Glass Co. v. Transmirra Products Corp.*, 353 U.S. 222, 77 S.Ct. 787, 1 L.Ed.2d 786 (1957), which held that for

purposes of 28 U.S.C. § 1400(b) a corporation resides only in its place of incorporation. Judge Weigel held that amendments to 28 U.S.C. § 1391(c) made a corporate defendant subject to patent infringement suit in any judicial district in which it is subject to personal jurisdiction. *Regents v. Lilly*, 734 F.Supp. 911, 14 U.S.P.Q.2d 1909 (N.D. Cal. 1990). The Federal Circuit has also adopted this interpretation of the amended venue statutes. *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574, 16 U.S.P.Q.2d 1614 (Fed.Cir.1990).

This decision held that venue in the Regents' infringement suit against Lilly was permissible in the Northern District of California; it did not hold that such venue was mandatory for all purposes, or that pretrial coordination in Indiana was barred.

(4) The decision of Judge Jensen of the Northern District of California in *Regents v. Lilly*, No. C90-0373, denying Lilly's motion to join Genentech as a necessary party.

Lilly had sought to bring into this California action a patent interference counterclaim involving a patent owned by Genentech. The Regents challenged Lilly's standing to assert such a counterclaim, and also asserted that in any event this counterclaim was barred by the Eleventh Amendment. The district court denied the joinder of Genentech. *Regents v. Lilly*, 777 F.Supp. 775, 19 U.S.P.Q.2d 1668 (N.D.Cal.1991).

The Regents argue that the district court's ruling established the absence of a relationship with Genentech as to this action. Lilly counters, and Regents does not seriously dispute, that this ruling was quite narrowly drawn, and did not reach the questions of commonality

of facts, witnesses, and parties pertinent to coordinated pretrial proceedings.

(5) The decision of Judge Jensen in Nos. C90-2232 and C90-0373 denying Genentech's motion to transfer *Regents v. Genentech and Lilly* to the Southern District of Indiana, and denying Lilly's motion to relate the two California actions.

In denying Genentech's motion to transfer under 28 U.S.C. § 1404(a),[4] the California district court observed that consolidation of all the cases for trial in Indiana was unlikely because they did not involve the same patents or claims of infringement, and because the Regents had requested a jury while the Indiana actions were being tried to a special master. *Regents v. Lilly*, 21 U.S.P.Q.2d 1201, 1207-08 (N.D.Cal.1991). The California court was not persuaded that Indiana was a more convenient forum for trial of this case since Genentech, the Regents, and many witnesses were located in California; since California law governs the contracts and trade secret agreements involved; and since *Regents v. Lilly*, which involves some of the same facts, would be tried in California. In declining the requested change of venue the Court did not hold that the California and the Indiana actions involved no common facts, parties, or witnesses.

The denial of a motion to transfer under § 1404(a) does not bar coordination of pretrial procedures under

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[4] **28 U.S.C. § 1404 change of venue**

(a) For the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought.

§ 1407. *See In re Air Crash Disaster at Toronto International Airport on July 5, 1970*, 346 F.Supp. 533 (J.P.M.L.1972) (granting transfer under § 1407 despite previous denial of a § 1404(a) transfer); *In re Aviation Products Liability Litigation*, 347 F.Supp. 1401, 1404 (J.P.M.L.1972) ("venue is not a criterion in deciding the propriety of transfer under Section 1407"). The considerations pertinent to a change of venue under § 1404(a) are not the same as those pertinent to coordination of pretrial proceedings in multiple cases involving common parties. *In re American Financial Corp. Litigation*, 434 F.Supp. 1232, 1234 (J.P.M.L.1977). Congressional intent is in accord. H.R. Rep. No. 1130, 90th Cong., 2nd Sess. (1968), *reprinted in* 1968 U.S.C.C.A.N. 1898, 1900.

The California district court had also considered Lilly's motion to relate the two California actions, *Regents v. Lilly* and *Regents v. Genentech and Lilly*, for trial before the same judge, in accordance with California Local Rule 205-2. The court held that the common elements of the two cases were insufficient to "relate" the actions, but that they were nevertheless sufficient to cause inconsistent and duplicative pretrial demands on parties and witnesses, such problems having already been encountered. *Regents v. Lilly*, 21 U.S.P.Q.2d at 1208. Accordingly, the court ordered that discovery in these California actions would be handled by the same magistrate.

However, the court did not reach the question of whether discovery in the California actions should also be coordinated with discovery in the Indiana actions. While the court considered it unlikely that all these actions could or should be consolidated for trial, and declined to transfer the California action to Indiana for

that purpose, it did not rule on whether they could or should be coordinated for pretrial proceedings.

The Regents express concern that Genentech and Lilly, upon pretrial coordination in Indiana under § 1407, will attempt to reopen various matters that were already decided in California – thereby getting an undeserved second bite. The Regents also express concern that Genentech and Lilly will maneuver to try the merits of the California actions in Indiana, for example by filing motions for summary judgment, thus defeating the Regents' expectation and entitlement that the merits of the California actions will be tried in California. These possibilities can not be evaluated in the abstract, and are not sufficient ground for reversing the § 1407 order of the Multidistrict Panel.

We conclude that principles of law of the case do not bar pretrial coordination of these five cases in accordance with § 1407, and transfer of the California cases to Indiana for this purpose.

III

The Regents state that the Multidistrict Panel is barred by the Eleventh Amendment from ordering pretrial coordination outside of the California forum. The Eleventh Amendment provides:

> The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State.

U.S. Const. amend. XI. The Regents have been described as an instrumentality of the State of California, *BV Engineering v. University of California, Los Angeles*, 858 F.2d 1394, 1395, 8 USPQ2d 1421, 1422 (9th Cir.1988), *cert. denied*, 489 U.S. 1090, 109 S.Ct. 1557, 103 L.Ed.2d 859 (1989).

In *Ex parte State of New York*, 256 U.S. 490, 497, 41 S.Ct. 588, 589, 65 L. Ed. 1057 (1921), the Supreme Court explained that the federal courts do not have authority to entertain a suit brought by private parties against one of the United States, without the State's consent. The Eleventh Amendment thus embodies principles of sovereign immunity, *Welch v. Texas Dep't of Highways & Public Transp.*, 483 U.S. 468, 486, 107 S.Ct. 2941, 2952, 97 L.Ed.2d 389 (1987), implementing the principles of federalism underlying the Constitutional plan. *Pennhurst State School and Hospital v. Halderman*, 465 U.S. 89, 100, 104 S.Ct. 900, 907, 79 L.Ed.2d 67 (1984).

A

The Regents argue that the Multidistrict Panel's order forces their participation in litigation to which they have not consented. This argument misperceives the nature of the transfer order. The order simply coordinates in one court, before one judge, the pretrial procedures of existing actions; it does not require the Regents to appear in actions to which they are not party, or to defend against claims to which they are not otherwise subject. The coordination of pretrial activities in pending proceedings, for the purpose of avoiding inconsistent and duplicative demands on parties, witnesses, and judges, neither

enlarges the State's liability nor invokes federal judicial power beyond that already sought by the State.

As discussed in *In re Aviation Products Liability Litigation*, 347 F.Supp. 1401, 1403-04 (J.P.M.D.L.1972), the transferee court is expected to tailor the pretrial program to fit the issues and parties, and to avoid subjecting any party to unrelated discovery or other procedures. The transferee court may cause pretrial proceedings on issues unique to a particular action to proceed on separate tracks concurrently with common pretrial proceedings, and has the power to provide that no party need participate in proceedings unrelated to that party's interests. *In re Cuisinart Food Processor Antitrust Litigation*, 506 F.Supp. 651, 655 (J.P.M.L.1981). The Panel's transfer order provides that the pretrial program in the Southern District of Indiana may allow discovery with respect to non-common issues to proceed concurrently with discovery on common issues. In response to the Regent's argument that an early trial is expected in the California actions, the Panel recognized: "It may be, on further refinement of the issues and close scrutiny by the transferee judge, that some claims or actions can be remanded in advance of the other actions".

We conclude that the Panel's order does not force unconsented suit upon the Regents, but simply coordinates pretrial proceedings, in the interest of efficiency.

B

The Regents also state that they limited their waiver of immunity to the venue of the Northern District of California, and that transfer of even part of the actions

they brought in California, for any purpose, is barred by the Eleventh Amendment.

The Eleventh Amendment is not designed to give procedural advantage to State litigants, but to shield States from unconsented actions against them. Although the Regents rely on *Port Authority Trans-Hudson Corp. v. Feeney*, 495 U.S. 299, 110 S.Ct. 1868, 109 L.Ed.2d 264 (1990):

> [I]ssues of venue are closely related to those concerning sovereign immunity, as this Court has indicated by emphasizing that "[a] State's constitutional immunity encompasses not merely *whether* it may be sued, but *where* it may be sued."

*Port Authority*, 495 U.S. at 307, 110 S.Ct. at 1873 (quoting *Pennhurst*, 465 U.S. at 99, 104 S.Ct. at 907), this reliance is inapt, for the two suits filed by the Regents in California are not "suit[s] . . . commenced or prosecuted against one of the United States", the words of the Eleventh Amendment. *See United States v. Peters*, 9 U.S. (5 Cranch) 115, 139, 3 L.Ed. 53 (1809) (Marshall, J.) (the right of a state to bring suit in federal courts is not affected by the Amendment; the Amendment simply provides that no suit shall be commenced or prosecuted against a state).

On filing these suits in the federal courts in California, the Regents requested adjudication of the claims that the State put before the court. *Clark v. Barnard*, 108 U.S. 436, 447, 2 S.Ct. 878, 883, 27 L.Ed. 780 (1883). Upon entering the litigation arena the Regents, like all litigants, become subject to the Federal Rules, including the procedural efficiencies administered by the Multidistrict Panel. Having invoked the jurisdiction of the federal

court, the state accepted the authority of the court. *See State of Iowa v. Union Asphalt & Roadoils, Inc.*, 409 F.2d 1239, 1244 (8th Cir. 1969).

We discern no principle of state sovereign immunity slighted by the Multidistrict Panel's order. Principles of federalism are not compromised by this result. Having sought the aid of the courts, the Regents became subject to coordinated pretrial proceedings under § 1407. While judicial efficiency can not override the Constitution, the coordination of pretrial procedures by a court, selected by a Panel constituted for this purpose, does not impinge upon the State's sovereign immunity.

IV

Having determined that this court has jurisdiction of this petition, that law of case is not implicated, and that the Eleventh Amendment does not bar the § 1407 procedure, we reach the merits of the Regents' petition for writ of mandamus.

Orders whose review is by extraordinary writ may be overturned only when there has been a clear abuse of discretion or usurpation of judicial authority. *See Bankers Life and Casualty Co. v. Holland*, 346 U.S. 379, 383, 74 S.Ct. 145, 148, 98 L. Ed. 106 (1953). The petitioner has the burden of establishing that its right to issuance of the writ is "clear and indisputable". *Will v. United States*, 389 U.S. 90, 96, 88 S.Ct. 269, 274, 19 L.Ed.2d 305 (1967); *In re Innotron Diagnostics*, 800 F.2d 1077, 1086, 231 USPQ 178, 185 (Fed. Cir. 1986).

The Regents argue that consolidation for pretrial proceedings should not be automatically ordered, but that all the circumstances of these five cases should be considered, including the present posture of each of the cases, their state of advancement toward trial, and the degrees of overlap and separateness of the issues. We agree that these considerations are pertinent; but they must be considered on the appropriate standard.

An order of coordination under § 1407 requires the presence of sufficient common questions of fact to promote just and efficient conduct of multiple actions by eliminating the potential for conflicting pretrial rulings by coordinate courts. The Multidistrict Panel was presented with evidence of overlap of documents and witnesses in the five actions. Although the Regents dispute the extent and significance of the overlap, there was evidence and argument that *Regents v. Genentech* (California) and *Genentech v. Lilly and Regents* (Indiana) involve at least some of the same issues of fact and law. *Regents v. Lilly* (California) is described as involving commercial activities of Lilly in producing human insulin using, in part, technology transferred to it by Genentech – this technology transfer partly underlies *Genentech v. Lilly* (Indiana). The agreements between the Regents and Lilly are involved in *Regents v. Lilly* (California), *Genentech v. Lilly* (Indiana), *Regents v. Genentech* (California), and *Genentech v. Lilly and Regents* (Indiana). A settlement agreement between the Regents and Genentech appears to be pertinent to *Regents v. Lilly* (California) and *Genentech v. Lilly* (Indiana). Various Genentech patents involved in *Lilly v. Genentech* (Indiana) are said to be asserted as invalidating prior art in *Regents v. Lilly* (California),

*Regents v. Genentech* (California), and *Genentech v. Lilly and Regents* (Indiana). Depositions of witnesses of all three entities are said to be pertinent to all five actions. At least thirty-five deposition witnesses that are said to be likely to be common to all five actions have been identified.

All of this, including argument as to the correctness or significance of representations of the three parties on these aspects, was before the Multidistrict Panel. The Panel was also advised of a complicated history involving certain protected documents, whereby there have already occurred duplicative rulings, multiple motions, and vacations of protective orders previously issued. Indeed, the holding of the California magistrate that certain relief requested for protected documents must be sought in Indiana weighs on the side of the Panel's order.

On review of the arguments and information provided us, we conclude that there was sufficient basis for the Multidistrict Panel's ruling that coordinated pretrial proceedings would best serve the objectives of 28 U.S.C. § 1407. The Panel's Order coordinating pretrial procedures was neither a clear abuse of discretion nor usurpation of judicial authority, nor contrary to law.

V

The Regents and Genentech join in arguing that if the Panel's coordination order is sustained, the Northern District of California, not the Southern District of Indiana, is the appropriate forum for the coordinated proceedings. They point out that two of the three parties are in California, and that the Northern District of California has the

less congested docket. *See In re Peruvian Road Litigation*, 380 F. Supp. 796, 798 (J.P.M.L.1974) (condition of court's docket is relevant factor in selection of transferee forum).

The Multidistrict Panel, recognizing that either district could be appropriate, concluded that the Southern District of Indiana was the better choice. The reasons were that the broader-based of these actions, as well as the earliest filed, were already in the Indiana court; that the Indiana court had developed more familiarity with the issues; that Indiana is a centrally located forum for witnesses located throughout the world and for counsel located on both coasts of the United States; and that many relevant documents and witnesses are at Lilly's headquarters in the Indiana district. These all are relevant factors. *See In re Republic National-Realty Equities Securities Litigation*, 382 F. Supp. 1403, 1406 (J.P.M.L.1974) (relevant to consider which district has a significant number of the underlying cases pending before it); *In re Plywood Antitrust Litigation*, 376 F. Supp. 1405, 1407 (J.P.M.L.1974) (relevant to consider familiarity of the judges with the issues); *In re Air Crash Disaster Near Coolidge, Arizona on May 6, 1971*, 362 F. Supp. 572, 573 (J.P.M.L.1973) (relevant to consider location of documents and witnesses); *In re Wheat Farmers Antitrust Class Action Litigation*, 366 F. Supp. 1087, 1088 (J.P.M.L.1973) (centrality of location a factor in choice of transferee forum). Lilly is the only party common to all five actions. *See In re Aviation Products*, 347 F. Supp. at 1404.

Although reasonable arguments have been made for both fora, the Regents and Genentech have not established that the Panel exceeded its discretionary authority in its selection of the Southern District of Indiana, and

have not shown a clear and indisputable right to selection of the Northern District of California as transferee forum.

ACCORDINGLY, IT IS ORDERED THAT:

The Regents' petition for writ of mandamus, ordering the Multidistrict Panel to vacate its order issued in accordance with § 1407, or alternatively to transfer the Indiana actions to the Northern District of California for coordinated pretrial proceedings, is DENIED.

## APPENDIX C

**United States Court of Appeals**
**for the Federal Circuit**

**ORDER**

**(Filed Oct. 24, 1997)**

A combined petition for rehearing and suggestion for rehearing in banc having been filed by the APPELLANT, and a response thereto having been invited by the court and filed by the APPELLEE, and the petition for rehearing having been referred to the panel that heard the appeal, and thereafter the suggestion for rehearing in banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the suggestion for rehearing in banc be, and the same hereby is, DECLINED.

The mandate of the court will issue on October 31, 1997.

FOR THE COURT,
JAN HORBALY, CLERK

Dated: October 24, 1997

By /s/ Alex Van Veen
Alex Van Veen
Staff Law Clerk

cc: ARTHUR I. NEUSTADT
DONALD R. DUNNER
NED A. ISRAELSEN

REGENTS OF UNIV OF CA V ELI LILLY, 96-1175 (DCT – 92-224)

Note: Pursuant to Fed. Cir. R. 47.6, this order is not citable as precedent. It is a public record.

## APPENDIX D

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

| | | |
|---|---|---|
| IN RE RECOMBINANT DNA TECHNOLOGY PATENT AND CONTRACT LITIGATION | ) ) ) ) | MDL DOCKET NO. 912 IP-92-0224-C |

Entry Granting Lilly's Motion to Transfer Cause Number IP-92-0224-C, and Denying UC's Request to Remand IP-92-0224-C to California

This cause comes before the Court on Lilly's motion to transfer cause number IP-92-0224-C to the Southern District of Indiana pursuant to 28 U.S.C. § 1404(a), and UC's request to remand IP-92-0224-C to California. For the following reasons, Lilly's motion to transfer is GRANTED, and UC's request to remand is DENIED.

### Background

The action presently before us is one of six cases consolidated in this Court for pretrial proceedings by the Judicial Panel on Multidistrict Litigation. *See In re Recombinant DNA Technology Patent and Contract Litig.*, Docket No. 912 (J.P.M.L. Feb. 19, 1992), *aff'd, In re Regents of the Univ. of Cal.*, 964 F.2d 1128 (Fed. Cir. 1992). The consolidated cases arise out of various research arrangements between the Regents of the University of California (UC), Genentech, Inc. (Genentech), and Eli Lilly & Company (Lilly).

Lilly moved the Court on October 5, 1993, to transfer cause number IP-92-0224-C to the Southern District of Indiana for trial, pursuant to 28 U.S.C. § 1404(a). On December 14, 1993, UC filed its opposition to Lilly's motion and requested the Court to remand the action to the Northern District of California upon close of discovery. This Entry discusses these issues.

## Discussion

Transfer of an action is appropriate (1) when the action might have been brought in the transferee court; and (2) when the transfer is for the convenience of the parties and witnesses and is in the interest of justice. 28 U.S.C. § 1404(a); *General Food Corp. v. Carnation Co.*, 411 F.2d 528, 532 (7th Cir.), *cert. denied*, 396 U.S. 940, 24 L.Ed.2d 242 (1969); *K & F Mfg. Co. Inc. v. Western Litho Plate & Supply Co.*, 831 F. Supp. 661, 664 (N.D. Ind. 1993). The parties do not dispute that this action originally could have been brought in the Southern District of Indiana. However, disagreements arise in their analyses of the second prong of the aforementioned test.

The Seventh Circuit has held that "[t]he 'interest of justice' is a separate component of a § 1404(a) transfer analysis, (citations omitted), and may be determinative in a particular case, even if the convenience of the parties and witnesses might call for a different result." *Coffey v. Van Dorn Iron Works*, 796 F.2d 217, 220 (7th Cir. 1986) (citations omitted). The focus of this separate component is on the efficient functioning of the courts. *Id.* at 221.

In the instant action, the issues are very complex. The motions already decided have required a great deal of

court time. Moreover, several motions *sub judice* will demand an equal or even greater amount of time. We believe that a transfer would better utilize judicial resources. For example, a transfer would prevent the Court in the Northern District of California from unnecessarily duplicating the judicial efforts thus far expended by this Court in gaining an understanding of the case. As we continue to decide additional discovery and substantive motions, we become more and more familiar with the action before us, as well as the other cases involved in this multidistrict litigation. Many of the issues involved in the instant suit are highly technical in nature. Because of this Court's growing familiarity with these and other issues, a transfer would promote judicial economy in all phases of the litigation. This economy would be realized whether some, all or none of the cases involved in this litigation eventually are consolidated for trial. Certainly, judicial efficiency weighs heavily in favor of transferring IP-92-0224-C to this Court.

Furthermore, "the preferred forum is that which is the center of the accused activity." *S.C. Johnson & Son, Inc. v. Gillette Co.*, 571 F. Supp. 1185, 1187-88 (N.D. Ill. 1983). " 'The trier of fact ought to be as close as possible to the milieu of the infringing device and the hub of activity centered around its production.' " *Id.* at 1188 (quoting *AMP Inc. v. Burndy of Midwest, Inc.*, 340 F. Supp. 21, 24-25 (N.D. Ill. 1971)). In the case before us, the record indicates that the only United States location in which Lilly uses the allegedly infringing process is Indianapolis. In addition, Lilly's research and production records related to this process are stored in Indianapolis. Consequently, these facts support a transfer.

UC and Lilly are in discord regarding the most convenient forum for parties and witnesses. UC argues for California, while Lilly insists that Indiana is the better choice. Each party has supported its respective position with a partial list of individuals its adversary has deposed. These lists are offered to illustrate to the Court the state in which the majority of the trial witnesses reside. We do not believe, however, that these lists are highly significant in our consideration of convenience. Although deposing an individual is an indication that a party to the litigation believes the deponent may have relevant information, yet the fact that an individual is deposed does not mean that he or she will be called to testify at trial. As Lilly points out in its reply brief, for example, several of the deponents UC has included in its list are not trial witnesses. *See* Lilly Reply Br. at 12-13.

In any event, we believe that in the interest of justice a transfer of this case to the Southern District of Indiana is appropriate. As earlier discussed, the element of judicial economy is afforded great weight. Thus, even were convenience of the parties and witnesses not advanced significantly, we still would be persuaded that a transfer is proper.

For the foregoing reasons, Lilly's motion to transfer is granted, and UC's request for a remand is denied.

Dated this 2nd day of March, 1994.

/s/ S Hugh Dillin
S. Hugh Dillin, Judge

## APPENDIX E

### *DOCKET NO. 912*

***BEFORE THE JUDICIAL PANEL ON MULTIDISTRICT LITIGATION***

***IN RE RECOMBINANT DNA TECHNOLOGY PATENT AND CONTRACT LITIGATION***

***BEFORE JOHN F. NANGLE, CHAIRMAN, S. HUGH DILLIN,* MILTON POLLACK,* LOUIS H. POLLAK, HALBERT O. WOODWARD,* ROBERT R. MERHIGE, JR., AND WILLIAM B. ENRIGHT, JUDGES OF THE PANEL***

### *TRANSFER ORDER*

This litigation consists of five actions listed on the attached Schedule A and pending in two districts as follows: three actions in the Southern District of Indiana and two actions in the Northern District of California. Genentech, Inc. (Genentech), a party to four of the five actions, moves the Panel, pursuant to 28 U.S.C. §1407, for an order centralizing the five actions in the Central District of California for coordinated or consolidated pretrial proceedings. Eli Lilly and Co. (Lilly), a party to all five actions, supports centralization but only in the Southern District of Indiana. The University of California (UC), the plaintiff in the California actions and the only other party in this docket, opposes any Section 1407 centralization.

On the basis of the papers filed and the hearing held, the Panel finds that the five actions in this litigation

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* Judges Dillin and Pollack recused themselves and took no part in the decision of this matter. Judge Woodward also took no part in the decision of this matter.

involve common questions of fact, and that centralization under Section 1407 in the Southern District of Indiana will best serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation. All actions stem from the involvement of UC, Genentech and Lilly in the scientific breakthroughs of the late 1970's involving recombinant DNA technology. UC and Genentech acquired patents relating to the technology, and agreements were executed concerning rights to various aspects of the technology. Eventually disputes erupted over the validity of patents and/or the terms of agreements, and this litigation ensued. The five actions now before the Panel are not identical in scope and share no common legal claim. Each action, however, will require an understanding of the complex nature of recombinant DNA technology and, either as a result of claims, counterclaims, third-party claims or defenses, will present factual questions that overlap with the other actions in this docket. Thus, for example, Genentech has identified 35 depositions common to all five actions, issues of patent validity pertaining to three patents that will be present in all actions, and a contractual settlement agreement whose interpretation will be involved in all actions. Centralization under Section 1407 is thus necessary in order to eliminate duplicative discovery, prevent inconsistent pretrial rulings, and conserve the resources of the parties, their counsel and the judiciary.

UC has objected that Section 1407 centralization would be economically burdensome, that unique issues are present in the California actions, that centralization would delay resolution of UC's claims, and that voluntary cooperation is a suitable alternative to transfer. We

find that these are not grounds for denying transfer. We point out that transfer under Section 1407 has the salutary effect of placing all actions in this docket before a single judge who can formulate a pretrial program that: 1) allows discovery with respect to any non-common issues to proceed concurrently with discovery on common issues, *In re Joseph F. Smith Patent Litigation*, 407 F. Supp. 1403, 1404 (J.P.M.L. 1976); and 2) ensures that pretrial proceedings will be conducted in a manner leading to the just and expeditious resolution of all actions to the overall benefit of the parties. It may be, on further refinement of the issues and close scrutiny by the transferee judge, that some claims or actions can be remanded in advance of the other actions in the transferee district. But we are unwilling, on the basis of the record before us, to make such a determination at this time. Should the transferee judge deem remand of any claims or actions appropriate, procedures are available whereby this may be accomplished with a minimum of delay. *See* Rule 14, R.P.J.M.L., 120 F.R.D. 251, 259-61 (1988).

While either of the two suggested transferee districts could be considered an appropriate transferee forum for this litigation, we are persuaded that the Southern District of Indiana is the preferable forum. In selecting this forum, we reject Genentech's suggestion that Section 1407 proceedings would advance at a faster pace in the California forum, and we note that: 1) the broader based and earliest filed actions are pending in the Southern District of Indiana; 2) the Indiana court has developed a familiarity with the issues in this litigation; 3) Indiana is a centrally located forum for witnesses located throughout the world and for counsel located on both coasts of the

United States; and 4) many relevant documents and witnesses are likely to be found at Lilly's headquarters located in the Indiana district.

IT IS THEREFORE ORDERED that, pursuant to 28 U.S.C. §1407, the actions listed on the attached Schedule A and pending in districts other than the Southern District of Indiana be, and the same hereby are, transferred to the Southern District of Indiana and, with the consent of that court, assigned to the Honorable S. Hugh Dillin for coordinated or consolidated pretrial proceedings with the actions listed on Schedule A and pending in that district.

FOR THE PANEL:

/s/ John F. Nangle
John F. Nangle
Chairman

## *SCHEDULE A*

***MDL-912 – In re Recombinant DNA Technology Patent and Contract Litigation***

Southern District of Indiana

*Eli Lilly and Co. v. Genentech, Inc.*,
C.A. No. 87-219-C
*Genentech, Inc. v. Eli Lilly and Co.*,
C.A. No. 88-1463-C
*Genentech, Inc. v. Eli Lilly and Co. and the Regents of the University of California*, C.A. No. 90-1697-C

Northern District of California

*Regents of the University of California v. Genentech, Inc.*,
C.A. No. C90-2232
*Regents of the University of California v. Eli Lilly and Co.*,
C.A. No. C90-0373

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Supreme Court, U.S.
FILED
FEB 20 1998
CLERK

No. 97-1201

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1997

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,

*Petitioner,*

v.

ELI LILLY AND COMPANY,

*Respondent.*

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit**

## RESPONDENT'S BRIEF IN OPPOSITION

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## QUESTIONS PRESENTED

1. Should the Court overturn as an abuse of discretion a decision of the Judicial Panel on Multidistrict Litigation ("JPML") consolidating five patent-related actions between Genentech Inc. ("Genentech"), the Regents of the University of California ("UC"), and Eli Lilly and Co. ("Lilly"): (1) where UC did not raise this issue before this Court by extraordinary writ as contemplated by 28 U.S.C. § 1407(e) and 28 U.S.C. § 1651; and (2) where there were hundreds of days of overlapping depositions, one of the patents asserted against Lilly by Genentech was the basis for Genentech's and Lilly's challenges to the validity and enforceability of UC's patents, and where the actions all required an understanding of complex biotechnology?

2. Should the Court reverse as an alleged violation of 28 U.S.C. §§ 1407(a) and 1404 an order of the multi-district transferee Court transferring the case to itself for trial even though: (1) UC waived this alleged defect by failing to raise it in its principal brief before the Federal Circuit; (2) UC failed to raise as one of its Questions Presented before this Court the propriety of the Federal Circuit's finding of waiver; and (3) the self-transfer practice is rooted in well established federal procedure and is not inconsistent with the spirit of the statute?

3. Are the Eleventh Amendment concerns raised by UC implicated where a state voluntarily enters the federal court system by suing a third party for patent infringement?

## PARTIES TO THE PROCEEDING BELOW

The parties are Petitioner, Regents of the University of California, and Respondent, Eli Lilly and Company. Eli Lilly and Company possesses neither a parent company nor any non-wholly owned subsidiaries.

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## OPINIONS BELOW

In addition to the opinions cited by UC, the opinion of the district court on the merits is reported at 39 U.S.P.Q.2d 1225 (S.D. Ind. 1995), and is annexed as Appendix A to Lilly's conditional cross-petition for certiorari served concurrently herewith.

## STATEMENT OF THE CASE

### I. INTRODUCTION

Contrary to UC's assertion that its scientists "paved the way for the production of recombinantly produced human insulin,"[1] it was Lilly and *not* UC that was the first to produce a safe and steady supply of human insulin created using "recombinant DNA" technology. Recombinant human insulin was developed and commercially introduced as the result of a collaborative project between Lilly and Genentech to which UC's scientists contributed *nothing*. Genentech, not UC, made and holds the basic patent on the recombinant DNA utilized by Lilly to make human insulin and human proinsulin. Lilly has already paid millions of dollars to Genentech for the right to practice under that patent.

UC nonetheless attempted to reap where it had not sown by suing Lilly in 1990 for allegedly infringing United States Patent Nos. 4,652,525 ("the '525 patent") and 4,431,740 ("the '740 patent"), seeking hundreds of millions of dollars for its alleged contribution to Lilly's sales of recombinant human insulin. After seven long years, both the United States District Court for the Southern District of Indiana and the United States

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[1] UC Pet. at 3.

Court of Appeals for the Federal Circuit thoroughly rejected such assertions by UC.

Throughout the litigation, UC sought to cloak itself in the mantle of a "pioneer." (UC Pet. at 2-3.) Yet, the evidence before the trial court established that the patents UC sought to enforce were rooted in inequity and deceit. While UC was the first to clone pieces of rat insulin DNA, it has now been proven that UC's original work upon which its patent position is based was conducted in knowing and willful violation of the applicable federal safety regulations governing recombinant DNA research. (Lilly Cross-Pet. at 3-9.) While UC's competition waited for government certification of the safety of the tools used in their recombinant DNA experiments, UC went forward using materials it knew had not been certified as safe by the government. *Id.* at 5-7. UC then misrepresented the origins of its data to the public, the National Institute of Health ("NIH"), the United States Senate, the United States Patent and Trademark Office ("PTO"), and the federal district court before which this action was tried, falsely claiming that the data had been obtained using certified materials. *Id.* at 5-8.

The trial court found UC's conduct sufficiently reprehensible that it refused to enforce the affected patent. *Id.* at 8-9. While the Federal Circuit reversed the trial court's unenforceability holding in the apparent belief that the misrepresentations were not material to any technical ground of unpatentability, it did not reverse as clearly erroneous any of the underlying factual findings of the trial court. (UC Pet. App. A at 23.)[2]

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[2] The Federal Circuit's treatment of the unenforceability issue represents a profoundly unwise public policy. It creates a large economic incentive for scientists to violate applicable federal safety regulations in the race for the vast economic reward associated with

Although UC's '525 patent purported to claim *all* the naturally occurring DNA sequences for proinsulin appearing in *any* mammal, UC had only experimentally determined and described a portion of the proinsulin DNA sequence for *rats*. The Federal Circuit, affirming the decision of the district court, specifically held that because, *inter alia*, one could not predict the structure of human or other mammalian DNA sequences based solely on the rat sequence, UC failed to demonstrate that it had actually invented the broad subject matter claimed by the '525 patent. (UC Pet. App. A at 17.) Accordingly, the Federal Circuit held that the claims of the '525 patent, which purported to encompass human DNA, were invalid for failing to satisfy the written description requirement of 35 U.S.C. § 112. *Id.*

Likewise, regarding UC's '740 patent, the Federal Circuit found that, during prosecution before the PTO, UC surrendered coverage of DNA sequences of the sort utilized by Lilly to produce human proinsulin. (UC Pet. App. A at 28.) Therefore, relying in part on this Court's decision in *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 117 S. Ct. 1040, 1049-51 (1997), the Federal Circuit held that UC could not recapture such subject matter in an infringement action. (UC Pet. App. A at 32.)

Without even challenging the merits of these decisions, UC seeks before this Court to undo the seven years of litigation it vigorously pursued against Lilly by raising alleged defects in *venue*. Yet, the Southern District of Indiana was undeniably a *proper* venue for the litigation. As the district in which Lilly

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securing U.S. patents on the fruit of illicit experimentation. Because this issue is of significant importance to the analogous current debate regarding the regulation of the cloning of human beings, Lilly has sought review in this Court, by way of a cross-petition for writ of certiorari filed concurrently herewith, of the Federal Circuit's enforceability holding.

has its principal place of business, it was a forum in which the infringement suit could have been brought originally under 28 U.S.C. § 1400(b). The Indiana district court also had both subject matter jurisdiction under 28 U.S.C. § 1338(a) and personal jurisdiction over Lilly. UC does not dispute these facts but instead complains about the particular procedural mechanisms that were used to transfer the case from the Northern District of California to the Southern District of Indiana. Specifically, UC challenges the validity of (1) an order by the JPML consolidating for pretrial proceedings UC's lawsuit against Lilly with four other factually related actions involving UC, Lilly, and Genentech pursuant to 28 U.S.C. § 1407, and (2) an order by the Southern District of Indiana transferring the trial venue from the Northern District of California to the multidistrict forum in the Southern District of Indiana pursuant to 28 U.S.C. § 1404(a).

There is, however, nothing remarkable about these two orders that justifies review by this Court. As will be discussed below, these orders were proper, were based on the particular factual circumstances of the parties, were in accordance with well-established law, and manifestly served the interests of justice by promoting judicial economy. Furthermore, the particular alleged defects in these orders raised by the first and second questions presented in UC's certiorari petition have *not* been properly presented to this Court for review. UC's third question presented in its petition asserts that the two transfer orders somehow violated UC's purported Eleventh Amendment immunity. However, contrary to UC's protestations, the Eleventh Amendment to the Constitution simply has no bearing on the instant case. Here, UC was a willing *plaintiff* in the litigation it initiated against Lilly, *not* a defendant compelled to litigate in federal court against its will. Thus, UC's reliance on principles of sovereign immunity are misplaced and are at odds with nearly two hundred years of precedent in this Court.

## II. LITIGATION HISTORY

In *The Regents of the University of California v. Eli Lilly and Co.*, UC sued Lilly in the Northern District of California for allegedly infringing its '525 and '740 patents. (UC Pet. App. A at 3.) Upon motion by Genentech, the JPML transferred the case in 1992 to the Southern District of Indiana pursuant to 28 U.S.C. § 1407 for coordinated pretrial proceedings with four other cases involving closely related technology, factual issues, documents, and witnesses.

Contrary to UC's contentions before this Court that there was "no common issue of material fact or law," the JPML specifically found that each action, in addition to requiring an understanding of recombinant DNA technology, "will present *factual questions that overlap with the other actions in this docket.*" (UC Pet. at i and App. E at 65, emphasis added.) The JPML explained that there were then thirty-five depositions common to all five actions, "issues of patent validity pertaining to three patents that will be present in all actions, and a contractual settlement agreement whose interpretation will be involved in all actions." *Id.* Based on these findings, the JPML correctly found that "[c]entralization under Section 1407 is thus necessary in order to eliminate duplicative discovery, prevent inconsistent pretrial rulings, and conserve the resources of the parties, their counsel and the judiciary." *Id.* Indeed, the JPML's decision was correct as there were ultimately *hundreds* of days of depositions which were attended by counsel for UC, Genentech, and Lilly.[3]

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[3] UC incorrectly asserts that the JPML's decision was inconsistent with the previous decision of the Northern District of California. Contrary to UC's contention, Lilly had *not* previously moved to transfer the case under § 1404(a) to the Southern District of Indiana. Lilly had instead moved to *dismiss* the case or in the *alternative* transfer because

Not satisfied with the JPML's decision, UC petitioned the Federal Circuit for a writ of mandamus to vacate the consolidation order. The Federal Circuit denied UC's request, finding that there was a sufficient basis for the JPML's decision due to numerous common factual questions between the actions, including the following:

> *Regents v. Lilly* (California) is described as involving commercial activities of Lilly in producing human insulin using, in part, technology transferred to it by Genentech--this technology transfer partly underlies *Genentech v. Lilly* (Indiana). The agreements between the Regents and Lilly are involved in *Regents v. Lilly* (California), *Genentech v. Lilly* (Indiana), *Regents v. Genentech* (California), and *Genentech v. Lilly and Regents* (Indiana). A settlement agreement between the Regents and Genentech appears to be pertinent to *Regents v. Lilly* (California) and *Genentech v. Lilly* (Indiana). Various Genentech patents involved in *Lilly v. Genentech* (Indiana) are said to be asserted as invalidating prior art in *Regents v.*

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it believed venue in the Northern District of California was *not proper* under 28 U.S.C. §§ 1391(c) and 1400(b). *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 734 F. Supp. 911, 912 (N.D. Cal. 1990). Likewise, although the Northern District of California did deny Lilly's motion to consolidate two of the cases in California between UC, Lilly, and Genentech, the district court *did* consolidate discovery in the two cases by transferring management of all discovery disputes to a single magistrate. 21 U.S.P.Q.2d 1201, 1208 (N.D. Cal. 1991). Accordingly, the Northern District of California's decision to consolidate the two cases for discovery is perfectly consistent with the JPML's decision to consolidate these two cases and the remaining three in Indiana for pretrial proceedings.

> *Lilly* (California), *Regents v. Genentech* (California), and *Genentech v. Lilly and Regents* (Indiana).

(UC Pet. App. B at 54-55.) Accordingly, based on these numerous relationships, the Federal Circuit held that UC failed to demonstrate that the JPML's decision was an abuse of discretion or a usurpation of judicial authority and denied UC's mandamus petition.

UC also challenged the JPML's consolidation on the grounds that it violated the Eleventh Amendment to the Constitution. The Federal Circuit, citing *United States v. Peters,* 9 U.S. (5 Cranch) 115, 139 (1809) (Marshall, J.), rejected this contention as well, holding that "[t]he Eleventh Amendment is not designed to give procedural advantage to State litigants, but to shield states from unconsented actions against them." (UC Pet. App. at 52). By commencing a suit against Lilly in federal court, the Federal Circuit explained, "the Regents, like all litigants, become subject to the Federal Rules, including the procedural efficiencies administered by the Multidistrict Panel." *Id.* UC accepted the Federal Circuit's ruling and did not seek further review in this Court by extraordinary writ as contemplated by 28 U.S.C. § 1407(e) and 28 U.S.C. § 1651.

After approximately two more years of discovery, and after the Southern District of Indiana—the multidistrict forum—had considered and denied *two* complex summary judgment motions brought by Lilly, the district court, pursuant to 28 U.S.C. § 1404(a) transferred the trial venue of the case to the Southern District of Indiana based primarily on considerations of judicial economy and the fact that the convenience of the parties and witnesses did not dictate a contrary forum. In rendering its decision, the district court

specifically found that (1) it had already gained an understanding of the complex technical issues involved in the case and it would be a waste of judicial resources to have another court duplicate this effort, (2) judicial efficiency heavily favored transferring the action due to the trial court's growing familiarity with such issues, and (3) that the center of the accused infringing activity was located in the multidistrict venue and thus is the preferred forum for trial. (UC Pet. App. D at 60-63.) In opposition to the transfer, UC argued that the transfer would not serve the interests of justice or the convenience of the parties, but did *not* then urge that such a transfer would violate what UC belatedly alleges is the "clear" language of § 1407.

After an additional year of discovery, and after the Southern District of Indiana considered and denied a third summary judgment motion brought by Lilly and a summary judgment motion brought by UC, the case was finally tried before Senior Judge S. Hugh Dillin. After a careful review of a 13,000 page trial record developed during a two week trial, receipt and evaluation of expert testimony from both sides, and observation of the demeanor of six expert witnesses, five of the inventors named on UC's patents, and three of UC's attorneys, Judge Dillin issued a lengthy and detailed opinion holding that UC's patents were either invalid, unenforceable, or not infringed by Lilly. (Lilly Cross-Pet. at App. A.)

On appeal, UC raised *nine* issues before the Federal Circuit. UC challenged the trial court's findings that: (1) the '525 patent was invalid; (2) the '525 patent was unenforceable; (3) the '525 patent was not infringed under the doctrine of equivalents; (4) the '740 patent was not literally infringed; (5) or, in the alternative, the '740 patent was invalid; (6) the '740 patent was not infringed under the doctrine of equivalents; and (7) the '740 patent was unenforceable. UC also asserted that

(8) the district court's § 1404 transfer violated the Eleventh Amendment, and (9) the district court failed properly to evaluate the considerations set forth in § 1404. Although UC was obviously not bashful regarding raising issues for appellate review, UC completely *failed* in its principal brief before the Federal Circuit to raise the issue of whether the transfer of the trial venue to the multidistrict forum violated § 1407.

After Lilly had filed its principal brief before the Federal Circuit, UC placed a single sentence in its *reply* brief belatedly alleging that the § 1404 transfer allegedly violated the statutory language of § 1407. Moreover, it was not until less than a week before oral argument that UC first cited Judge Kozinski's dissent in *In re American Continental Corp./Lincoln Savings & Loan Securities Litigation, 102 F.3d* 1524 (9th Cir. 1996), *cert. granted in part sub nom. Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach,* 117 S. Ct. 1818 (1997), to the Federal Circuit. Because UC failed to raise this issue in its principal brief or at any earlier time during the litigation, Judge Bryson of the Federal Circuit specifically questioned UC's counsel, at oral argument, on the issue of whether this argument had been waived. In response to Judge Bryson's question regarding whether UC had properly raised this argument in its opening brief, UC's counsel— effectively *admitting* that it had waived the argument—stated "the exact answer to your honor's question is no we did not."

Seven months later, the Federal Circuit delivered a 33 page opinion holding that the '525 patent was invalid and that Lilly had not infringed the properly interpreted claims of the '740 patent. Regarding UC's challenge to whether the district court properly evaluated the criteria set forth in § 1404(a), the Federal Circuit explained that "in a case such as this in which several highly technical factual issues are presented and the other relevant factors are in equipoise, the interest of judicial

economy may favor transfer to a court that has become familiar with the issues." (UC Pet. App. A. at 11.) The Federal Circuit also held, as it did before, that "the Eleventh Amendment applies to suits 'against' a state, not suits by a state," and that "we do not believe that the Court has ever so construed the Eleventh Amendment [as applying to suits brought by a state]." (UC Pet. App. A. at 9.)

Furthermore, the Federal Circuit, citing its own established precedent, found that UC, by failing to raise the issue in its opening brief, *waived* its argument regarding whether § 1407 allowed a multidistrict transferee court to transfer a case to itself for trial under § 1404(a). (UC Pet. App. A at 11-13.) UC filed a petition for reconsideration with a suggestion for rehearing in banc, which did not raise any of the issues now before the Court. Finally, UC filed its petition for writ of certiorari on January 21, 1998.

## REASONS FOR DENYING THE WRIT

The Court should not expend its extremely limited resources by examining the propriety of the pretrial consolidation by the JPML, which is the subject of UC's first question presented in its petition. This issue has not been properly raised and is fundamentally a factual dispute not worthy of Supreme Court review. The JPML properly determined that, due to the many overlapping witnesses and the common factual issues involved in the actions between UC, Genentech, and Lilly, the five separate actions should be consolidated for pretrial proceedings to promote judicial economy and serve the interests of justice. On a petition for a writ of mandamus, the Federal Circuit in *1992* reviewed the merits of the consolidation order and after a full and fair hearing held that the JPML had not abused its discretion. Now, six years later, after voluminous discovery, a legally and

technically complex trial, and an appeal to the Federal Circuit, UC asks this Court to review the findings of the JPML and the Federal Circuit. UC, however, did not raise the validity of the multidistrict consolidation to this Court *at that time* as contemplated by § 1407(e) and § 1651. Accordingly, this Court should decline to consider at this late date the circumstances regarding the pretrial consolidation. Furthermore, and perhaps more importantly, this issue is simply not worthy of this Court's review. UC's argument represents a mere *factual* challenge to the findings of the JPML—findings that were approved by the Federal Circuit—regarding the interrelations between the five actions and does *not* raise a unique question of law warranting review by this Court.

UC's challenge to the Southern District of Indiana's so-called "self transfer"—the second question presented in UC's petition—is also not properly before the Court. UC contends in its petition that the allegedly "plain language and clear legislative history"[4] demonstrate that a § 1407 transferee court cannot transfer the case for trial to the multidistrict venue pursuant to 28 U.S.C. § 1404(a). This issue is currently before the Court in *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 117 S. Ct. 1818 (1997). However, UC fails to explain why, despite this alleged "plain language," it failed to raise this issue until after both parties had filed their principal briefs on the merits on appeal before the Federal Circuit. Since UC did not raise this issue in its opening brief, the Federal Circuit, following its own well-established precedent, held that UC had waived this venue argument. Thus, before this Court reaches this issue on the merits, it must first determine whether the Federal Circuit correctly found that UC waived this issue. This question, however, is not included in UC's petition for certiorari

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[4] UC Pet. at 17.

and is not "fairly included therein" under the rationale of *Yee v. Escondido,* 503 U.S. 519, 537 (1992). Accordingly, this Court should not even reach UC's second question. Moreover, even if the Court addresses this issue, it should not disturb the Federal Circuit's opinion because (1) UC did in fact waive this venue issue and (2) the self-transfer practice is not in conflict with the statutory framework for reasons cited by the respondent and supporting *amici* in the *Lexecon* case.

Finally, the Eleventh Amendment concerns raised by UC—UC's third question—simply have no bearing on the issues in this case. The Eleventh Amendment immunity to which UC clings simply does not apply where a state is a willing plaintiff in federal court. Accordingly, for all of the foregoing reasons, this Court should deny UC's petition for a writ of certiorari.

## I. UC'S FIRST QUESTION DOES NOT WARRANT REVIEW BY THIS COURT

UC's first question asks whether the Federal Circuit erred by declining to overturn an order of the JPML, which consolidated for coordinated pretrial proceedings five then-pending lawsuits involving UC, Genentech, and Lilly. This question, however, does not merit further attention by this Court because: (1) UC failed to seek timely review of the Federal Circuit's denial of its petition for a writ of mandamus; and (2) the question raises mere factual issues that have already been considered and appropriately resolved by the JPML and the Federal Circuit.

A. Review Now Is Untimely

UC did not petition this Court to review the Federal Circuit's denial of its mandamus petition *at the time of the decision.* UC instead allowed the parties and the federal courts to expend years of effort in discovery, trial preparation, trial practice, and appellate practice, the results of which UC now finds unsatisfactory. If UC had a continuing objection to coordinated pretrial proceedings, it had a duty to raise those objections promptly before this Court by application for an extraordinary writ. Because UC did not do so, prudential considerations weigh heavily against reviewing the propriety of the JPML at this late date. In enacting § 1407(a), Congress sought "to provide centralized management under court supervision of pretrial proceedings of multidistrict litigation to assure the 'just and efficient conduct' of such actions."[5] Such centralized management, it was hoped, would avoid or minimize the possibility for conflict or duplication of discovery during pretrial proceedings. *Id.* at 1899-1900. Although Congress identified a number of factors relevant to the application of a § 1407(a) transfer, it recognized that such factors "do not lend themselves to precise measurement," and that "the informed discretion of the judiciary is the best method for resolving questions as to when and where cases should be transferred for pretrial [proceedings]." *Id.* at 1901.

Accordingly, to best effectuate its overall purpose of promoting judicial economy, Congress expressly opened, yet also carefully circumscribed, a specific path for judicial review of JPML decisions under § 1407(e). Under the express language of 28 U.S.C. § 1407(e), "[n]o proceedings for review

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[5] *See* H.R. No. 1130, 90th Cong., 2d Sess. 2 (1968), *reprinted in* 1968 U.S.C.C.A.N 1898, 1899.

of any order of the panel may be permitted except by extraordinary writ pursuant to the provisions of title 28, section 1651, United States Code." By limiting review to this procedural mechanism, dissatisfied litigants were given a simple choice: either pursue immediate judicial review, in the nature of mandamus under 28 U.S.C. § 1651, or go forward with pretrial proceedings in the transferee district.[6]

Although UC petitioned to the Federal Circuit for mandamus under § 1651, it did *not* seek review from this Court of the Federal Circuit's denial of its mandamus petition by extraordinary writ as contemplated by § 1407(e). 28 U.S.C. § 1651(a) undeniably provides this Court with the authority to act upon an appropriate application under § 1407(e).[7] Because an appropriate method of obtaining review by this Court existed at that time, UC should not be permitted to avoid the procedural mechanism specifically enacted by Congress for review of § 1407(a) transfer orders. Indeed, logic dictates that if UC desired to petition this Court for review, it should have done so at the time of the Federal Circuit's denial of its mandamus petition, *not* six years later—after discovery, a trial on the merits, and an appeal to the Federal Circuit. Review of the JPML's consolidation order at this late date utilizing the "normal" certiorari route would seriously conflict with Congress' intent of permitting review of the JPML's orders only in a manner which promotes the policy of judicial economy

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[6] 1968 U.S.C.C.A.N. at 1902 (mandamus "is more expeditious than appeal, and is consistent with the overall purposes of the proposed statute").

[7] Section 1651(a) states that "The Supreme Court . . . may issue all writs necessary or appropriate in aid of [its] jurisdiction[] and agreeable to the usages and principles of law."

underlying § 1407. Accordingly, this Court should decline to review UC's first question presented.[8]

B. UC's Challenge is Merely Factual

UC asserts that the JPML abused its discretion and/or exceeded its statutory authority by consolidating the five actions between Genentech, UC, and Lilly because—according to UC—there were no common factual questions involved in the actions. The fundamental flaw in UC's argument, however, is that the there *were* numerous factual overlaps between the actions, including *hundreds* of days of common depositions and *thousands* of common documents. Indeed, UC completely ignores the specific findings of the JPML and the Federal Circuit regarding these factual overlaps. (UC Pet. App. B. at 54-55; UC Pet. App. E at 65.)[9] In this regard, the JPML specifically stated that the five actions, in addition to requiring an understanding of recombinant DNA technology, "will present *factual questions that overlap with the other actions in*

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[8] Even if this Court determines that UC did not have to raise this issue to the Court at an interlocutory stage of the proceeding, UC should have raised this issue again to the Federal Circuit on appeal after trial. *See* Robert L. Stern et al., *Supreme Court Practice*, 198 (7th ed. 1993)("Denial of certiorari at the interlocutory stage of a proceeding is without prejudice to renewal of the questions presented when certiorari is later sought from the final judgment, *assuming the questions are properly preserved in the lower courts after the denial.*")(emphasis added). As UC chose not to raise this issue before the Federal Circuit, review here is no longer appropriate.

[9] Due to these factual overlaps, UC's reliance on *In re Repetitive Stress Injury Litigation*, 11 F.3d 368, 373 (2d Cir. 1993) is misplaced.

*this docket.*" (UC Pet. App. E at 65, emphasis added.)[10] Thus, as UC's petition represents a mere factual challenge to the record already reviewed by the JPML and the Federal Circuit, it should not be reviewed by this Court pursuant to well-established precedent.[11]

## II. UC's SECOND QUESTION REGARDING THE PROPRIETY OF SELF-TRANSFER IS NOT PROPERLY BEFORE THE COURT

### A. UC Failed Properly to Present the Waiver Issue as a Question to this Court

This Court's Rule 14.1(a) specifically states that "[o]nly the questions set out in the petition, or fairly included therein, will be considered by the Court." Accordingly, "[t]he framing

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[10] Although Lilly could spend many pages discussing the numerous factual interconnections between the five actions, Lilly will merely note that published European patent application EPA-1929, the foreign counterpart of one of the patents that was in suit in the Indiana patent action between Genentech and Lilly (U.S. Patent No. 4,704,362 issued in the names of Itakura and Riggs) provided the basis for Lilly's defenses in the instant case that UC's '740 patent was both invalid and unenforceable and Genentech's defense in its litigation with UC that UC's growth hormone patent was unenforceable. Thus, one of the critical issues in all the cases was the scope and content of this patent's disclosure and the factual circumstances involving UC's knowledge of this patent.

[11] *Graver Tank & Mfg. Co., v. Linde Air Prod. Co.*, 336 U.S. 271, 275 (1949)(stating that "[a] court of law, such as this Court is, rather than a court for correction of error in fact finding, cannot undertake to review concurrent findings of fact by two courts below in the absence of a very obvious and exceptional showing of error"); *Goodman v. Lukens Steel Co.*, 482 U.S. 656, 665 (1987).

of the question presented has significant consequences" since the Court does not ordinarily "consider questions outside those presented in the petition for certiorari." *Yee v. Escondido,* 503 U.S. 519, 535 (1992); *Izumi Seimitsu Kogyo Kabushiki Kaisha v. U.S. Philips Corp.,* 510 U.S. 27, 31-32 (1993). Although this rule is prudential in nature, the Court will only disregard it "in the most exceptional cases." There are two principal reasons for the rule: (1) it provides notice to the respondent of the grounds upon which the petitioner seeks certiorari; and (2) it assists the Court in granting certiorari in only those cases that enable the Court to "resolve particularly important questions." *Yee*, 503 U.S. at 535-36.

In the instant case, UC failed to present to the Court the question of whether the Federal Circuit erred in finding that UC waived the so-called *Lexecon* self-transfer argument. Instead, UC only raised the self-transfer issue on the merits: whether the language of § 28 U.S.C. 1407(a) permitted the multidistrict judge to transfer the trial venue of the case to the multidistrict forum under 28 U.S.C. § 1404(a). An almost identical situation was presented to the Court in the *Izumi* case. In *Izumi*, the petitioner presented one question for review by the Court: "Should the United States Court of Appeals routinely vacate district court final judgments at the parties' request when cases are settled while on appeal?" *Izumi*, 503 U.S. at 30. However, in order to reach this question, the Court first had to decide the following standing question later raised by petitioner: "Whether the court of appeals should have permitted Petitioner to oppose Respondents' motion to vacate the district court's judgment?" *Id.* The Court explained that if the later raised question is not fairly included in the initial question presented for review, then "Rule 14.1 would prevent us from reaching it." *Id.* at 31.

The Court found that the second question was *not* "subsidiary" or "fairly included" in the initial question, explaining that the later raised question is a threshold inquiry akin to a question regarding a party's standing, in "no way depends on the merits" of the case, and is "analytically and factually" quite different from the question on which review was granted. *Id.* at 31-32. Moreover, the Court noted that the analysis is not affected by the fact that the parties discussed the question in their briefs, stating that this "fact . . . does not bring that question properly before us." *Id.* at 31 n.5. Thus, this Court held that Rule 14.1(a) imposed a heavy presumption against considering the second question. Although acknowledging that there are exceptions to this general rule, the Court found that none of those exceptions applied because a decision on a motion to intervene—the later raised question—is a difficult one, is bound up in the facts of the case, and is unlikely to result in a new principle of law. *Id.* at 33. Therefore, since the later raised intervention issue needed to be addressed *before* the Court could address the question that was properly presented, the Court dismissed its writ of certiorari as improvidently granted. *Id.* at 34.

Likewise, this Court should not grant certiorari on the self-transfer issue raised by UC's second question presented. To reach this question, the Court must first hold that the Federal Circuit erred in finding that UC waived the self-transfer argument. However, as in *Izumi,* this threshold issue was *not* properly presented as a question to this Court. Moreover, the waiver issue is not "fairly included" in the question on the merits presented by UC. As was the case in *Izumi*, the waiver issue is a threshold inquiry which in no way depends on the merits of the case and is factually and analytically distinct from UC's second question on the merits. To determine that the Federal Circuit erred regarding the waiver issue, this Court would have to examine both the Federal Circuit's precedent on

briefing requirements and waiver and the factual circumstances regarding UC's failure to raise the self-transfer issue at any time before its reply brief at the Federal Circuit. This analysis is completely separate and distinct from the question of whether the language and legislative history of § 1407(a) allows self-transfer. Furthermore, there are not sufficient reasons in the instant case to overcome the "heavy presumption" against reviewing an issue not fairly included in the question presented. As in *Izumi*, the question regarding whether UC waived the issue is bound up in the facts of the case and is unlikely to establish a new principle of law. Moreover, the legal question raised by UC on the merits has already been raised in the *Lexecon* case. Thus, there is no compelling need for the Court to now address this issue. Accordingly, this Court should not reach this issue and thus should not grant certiorari on UC's second question presented.

B. UC Waived the Self-Transfer Argument Set Forth in its Second Question Presented

Even if this Court reaches the question of waiver, certiorari on the merits is not warranted. The Federal Circuit correctly found that UC waived this issue. UC asserts that the "plain language and clear legislative history of Section 1407(a)" indicates that the district court should have remanded the case to the Northern District of California rather than transferring the trial venue to the Southern District of Indiana pursuant to § 1404(a). (UC Pet. at 17.) However, UC provides no satisfactory explanation why, if the language is so clear, it first raised this issue in its reply brief before the Federal Circuit. In this regard, UC's position is remarkably different from that of the petitioner in *Lexecon,* which raised the issue regarding the statutory language of § 1407 by writ of mandamus to the Ninth Circuit immediately after the allegedly improper transfer and again to the Ninth Circuit on appeal of the merits. If Lexecon

could properly raise these arguments, there is apparently no reason why UC could not have done the same.

It is the well-established practice in the Federal Circuit, as in many other courts of appeals, that issues not raised in a party's principal brief are waived. *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 800 (Fed. Cir. 1990) ( "[A]n issue not raised by an appellant in its opening brief . . . is waived."); *see also Kaufman Co. v. Lantech, Inc.*, 807 F.2d 970, 973 (Fed. Cir. 1986)("We note here that it is inappropriate for appellants to discuss in their reply brief matters not raised in either of the principal briefs."); *Conopco, Inc. v. May Dep't Stores Co.*, 46 F.3d 1556, 1561 n.1 (Fed. Cir. 1994). For this reason, the Federal Circuit specifically questioned UC's counsel at oral argument regarding whether it had properly raised the self-transfer argument in its opening brief. As previously mentioned, *see* p. 9, *supra*, UC conceded that it did not raise this argument in its opening brief and thus effectively *admitted* that it waived the argument under well-established practice and precedent of the Federal Circuit.

In response, UC argues *not* that it had properly raised the issue of whether the language and legislative history of § 1407(a) precluded self-transfer, but instead that it had raised *other* venue challenges before the Federal Circuit. Specifically, UC cites its contentions that Judge Dillin failed properly to evaluate the criteria set forth in § 1404(a) (whether the transfer was for the convenience of the parties and in the interests of justice) and whether the transfer violated UC's alleged Eleventh Amendment immunity from suit. Indeed, UC suggests, citing *Lebron v. National R.R. Passenger Corp.*, 513 U.S. 374, 379 (1995), that even if the Federal Circuit correctly found that UC had waived this issue, review by this Court is still proper because UC had raised these other venue issues. (UC Pet. at 16-17.)

Yet, *Lebron* provides no support for UC's position. The Court in *Lebron* merely found that "once a claim is properly presented, a party can make any argument in support of that claim." 513 U.S. at 379. UC, however, did *not* raise its claim regarding the statutory language of § 1407 in a timely manner before the Federal Circuit. UC only challenged whether the district court correctly applied the criteria of § 1404 and whether such a transfer violated the Eleventh Amendment. In contrast, UC now seeks to broaden its claim to include *all* challenges to the venue of the trial. Such efforts should not be countenanced by this Court. Indeed, the Federal Circuit has a similar rule to the one cited in *Lebron* but nevertheless found that UC had waived this argument.[12]

Moreover, in an analogous situation, this Court has found that a claim regarding whether there had been a *regulatory* taking was analytically different and *not* fairly included in a claim regarding whether there had been a *physical* taking. *Yee,* 503 U.S. at 537. The Court specifically held that "[b]oth might be subsidiary to a question embracing both—Was there a taking?—but they exist side by side, neither encompassing the other." *Id.* In the same way, UC's arguments that Judge Dillin did not properly apply the criteria in § 1404(a) and that the transfer was unconstitutional do not encompass the analytically separate question of whether § 1407(a) requires remand.

Furthermore, the Court in *Lebron* specifically discussed the previous decision in *Yee* and distinguished *Yee* on the following grounds: (1) that it was possible in *Yee* to consider

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[12] *See Consolidated Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 814 (Fed. Cir. 1990) (judgment may be defended on any ground properly raised below).

whether there was a physical taking without inquiring into whether there was a regulatory taking but in *Lebron* it was "impossible" to consider whether Amtrack's government connections were sufficient to convert Amtrack from a private-entity into the Government without first determining that Amtrack was a private entity; and (2) that while in *Yee* "what would go to show a regulatory taking and what would go to show a physical taking were quite different," in *Lebron,* the elements that the Court would consider in determining whether Amtrack was converted into the Government or whether it was the Government to begin with are closely related and overlap. 513 U.S. at 381-82. In the instant case, it is obviously possible to determine the § 1404 issues raised by UC without considering the question of whether § 1407 requires remand since this is exactly what was done by the Federal Circuit. Moreover, as in *Yee*, the analysis of whether the transfer was for the convenience of the parties and in the interests of justice and whether it violated the Eleventh Amendment are separate and do not overlap with the question regarding the meaning of the language and legislative history of § 1407(a).[13] Accordingly, the Court's decision in *Lebron* does not excuse UC's failure to raise this issue before the Federal Circuit.

Finally, as to the merits of UC's position, it is Lilly's position that the JPML's rule allowing self-transfer by the § 1407 transferee court is consistent with both the text and legislative history of 28 U.S.C. § 1407 and serves the interests

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[13] In addition, another reason why the Court in *Lebron* decided to review the issue was that it was passed upon by the Second Circuit. *Id.* at 379; *Lebron v. National R.R. Passenger Corp.*, 12 F.3d 388, 390 (2d Cir. 1993)(holding that "Government action is most readily found when the conduct at issue is performed by a government entity . . . that is not the case here"). In the instant case, however, the Federal Circuit did not pass on the issue, finding that it had been waived by UC.

of justice. Indeed, contrary to UC's assertions, Lilly submits that the instant case graphically illustrates the proper functioning of the multidistrict litigation system, as envisioned by Congress, by disposing of unmeritorious claims in the most efficient and expeditious manner possible. Lilly's views on this issue are amply reflected in its *amicus* brief, as well as the brief of the Respondent in the *Lexecon* case. Lilly will not burden this brief with a recapitulation of those views. Suffice it to say that if this Court does not strike down the now well-established practice of self-transfer in the *Lexecon* case, UC's arguments will necessarily fail as a matter of law. Yet, even if this Court were to rule in *Lexecon* that self-transfer is improper, UC's petition must still be denied because UC, unlike the petitioner in *Lexecon*, waived this argument.

## III. ELEVENTH AMENDMENT CONCERNS ARE NOT IMPLICATED BY THIS CASE

In its petition for certiorari, UC seeks to portray itself as a helpless state litigant whose sovereign immunity has been swept away by the flawed application of 28 U.S.C. §§ 1407 and 1404. UC contends that the JPML's pretrial consolidation under § 1407 and the transfer of the trial venue to the multidistrict forum under § 1404(a) deprived a sovereign of its right to select a forum for its litigation and thereby violated the Eleventh Amendment to the Constitution. (UC Pet. at 17-18.) This argument, however, flows from UC's erroneous view that principles of sovereign immunity are somehow implicated where a state is a *willing plaintiff* in federal court. UC's novel theory is not only directly contradicted by the jurisprudence of this Court but also subverts the very policies underlying the Eleventh Amendment.

The Eleventh Amendment was enacted as a direct response to this Court's decision in *Chisholm v. Georgia*, 2 U.S.

(2 Dall.) 419 (1793), which allowed a South Carolina citizen to *sue* the state of Georgia in federal court to recover debts for materials supplied during the Revolutionary War.[14] To overturn the result of this case, the Eleventh Amendment prohibits citizens of another state, or of the same state, from *suing an unconsenting state* in federal court. The Eleventh Amendment embodies the Constitutional policy that "each State is a sovereign entity in our federal system" and that "it is inherent in the nature of sovereignty not to be amenable to the suit of an individual without its consent." *Seminole Tribe of Florida v. Florida*, 116 S. Ct. 1114, 1118 (1996). The sovereignty of the State of California, however, cannot be violated when, as in this case, the state itself purposefully chooses to bring suit in federal court. *United States v. Peters*, 9 U.S. (5 Cranch) 115, 139 (1809).

In *United States v. Peters,* Justice Marshall, writing only eleven years after the ratification of the Eleventh Amendment, discussed the scope of this doctrine in a case where the State of Pennsylvania had asserted that federal courts were without jurisdiction. In addressing the state's arguments, Justice Marshall specifically stated the following:

> The right of a state to assert, *as plaintiff*, any interest it may have in a subject, which forms the matter of controversy between individuals, in one of the courts of the United States, is not affected by this amendment; nor can it be so construed as to oust the court of its jurisdiction, should such claim be suggested. *The*

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[14] *Principality of Monaco v. Mississippi*, 292 U.S. 313, 325 (1934); *see* Erwin Chemerinsky, *Federal Jurisdiction*, § 7.2 at 330-32 (1989).

> *amendment simply provides, that no suit shall be commenced or prosecuted against a state.*

*Id.* at 139, emphasis added. Contrary to UC's assertions, this statement directly addresses and thoroughly rejects UC's assertion that the Eleventh Amendment applies where a state is a willing plaintiff in federal court. Indeed, UC has failed to cite one case in the two hundred years since its ratification where the Eleventh Amendment was invoked in a situation such as this where the state brought the suit.

The cases cited in UC's petition for certiorari involve situations where the state was the defendant, *not* the plaintiff.[15] Moreover, much of UC's cited authority pertains to the level of intent necessary for a state to effectuate a *waiver* of its Eleventh Amendment immunity. Such principles of *waiver* are simply not applicable because the Eleventh Amendment immunity does not apply where the state is a willing plaintiff. Moreover, the venue concern implicated by the cases cited by UC is whether the state consented to be sued in federal court or state court, *not* whether consent to proceedings in one federal court

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[15] *See e.g., Seminole Tribe v. Florida*, 116 S. Ct. 1114 (1996) (suit against State of Florida); *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89 (1984) (suit against officials of State of Pennsylvania); *Port Authority Trans-Hudson Corp. v. Feeney*, 495 U.S. 299, 307 (1990) (suit against entity created by States of New York and New Jersey); *Hans v. Louisiana*, 134 U.S. 1 (1890) (suit against state of Louisiana); *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234 (1985) (suit against California State Hospital and California State Agency); *In re New York*, 256 U.S. 490, 496 (1921) (suit against state of New York).

could preclude transfer to another federal court as suggested by UC. [16]

Thus, the clear text of the Eleventh Amendment and the jurisprudence of this Court provide no support for UC's novel interpretation regarding the scope of the Eleventh Amendment immunity from suit. UC attempts to bolster its position by resorting to strained policy arguments. UC asserts that the Federal Circuit ignored "the broad principles underpinning the Amendment" and instead "focused myopically on the precise words," giving the Eleventh Amendment a "narrow, wooden, construction." (U.C. Pet. at 21-22.) UC, however, fails to demonstrate how the Federal Circuit's determination contravenes *any* important policy.

Indeed, the Federal Circuit's decision is perfectly consistent with this Court's precedent that citizens of the same state,[17] foreign sovereigns,[18] and federal corporations cannot *sue* a state in federal court.[19] All of these decisions reflect the

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[16] *See, e.g., Port Authority Trans-Hudson Corp.*, 495 U.S. at 307 (holding that the states of New York and New Jersey consented to be sued in *federal* court, rather than *state* court, and thereby waived their Eleventh Amendment immunity); *Pennhurst State Sch. and Hosp.*, 465 U.S. at 99 n.9 ("[T]he Court consistently has held that a State's waiver of sovereign immunity in its own [state] courts is not a waiver of the Eleventh Amendment immunity in the federal courts."); *Atascadero State Hosp.*, 473 U.S. at 241 ("[I]n order for a State statute . . . to constitute a waiver of Eleventh Amendment immunity, it must specify the State's intention to subject itself to suit in *federal court*.").

[17] *Hans v. Louisiana*, 134 U.S. 1 (1890).

[18] *Principality of Monaco v Mississippi*, 292 U.S. 313 (1934).

[19] *Id.* at 327.

policy that a sovereign should not be compelled into the courts of another sovereign against its will. These decisions have absolutely nothing to do with the instant case where a state voluntarily entered the federal court system by suing a third party. In this regard, the Federal Circuit specifically stated that "we do not believe that the Court has ever so construed the Eleventh Amendment" to apply to situations where the state is a willing plaintiff. (U.C. Pet. App. at 9.) Accordingly, the Federal Circuit—applying the uniform precedent of this Court—correctly held that "the Eleventh Amendment applies to suits 'against' a state, not suits by a state" and that "[t]he Eleventh Amendment is not designed to give procedural advantage to State litigants, but to shield States from unconsented actions against them." (U.C. Pet. App. at 9, 52.)

UC further argues that there is a "blurring" of the defendant-plaintiff roles in patent cases which somehow justifies an expansion of the Eleventh Amendment beyond its intended scope. As the patent holder, UC asserts that it must *defend* its patents against charges of invalidity and unenforceability. (UC Pet. at 24.) Thus, according to UC, its role in patent cases is like that of a traditional defendant. *Id.* UC's contentions are without merit. In this case, there was no legal charge or proceeding initiated by Lilly attacking UC's patents. There was only a refusal by Lilly to acquiesce in UC's assertion that it had a property right which Lilly was infringing. UC chose to go to federal court to enforce its asserted property right, just as every plaintiff in commercial civil litigation goes to court to assert some property or contract right which its adversary refuses to acknowledge. If UC's argument were accepted, the plaintiff in every such commercial case could be viewed as the *de facto* defendant, leading to a series of facially absurd results.

Moreover, contrary to UC's assertion, there is nothing that compels a state entity to own patents or to sue alleged infringers. UC suggests that "[i]n these days of diminishing public resources," state universities often patent their discoveries to create income for additional basic research. (UC Pet. at 19.) UC then asserts that it "must" file suit in federal court or forego an important public asset–hypothetical royalties from an alleged infringer. *Id.* at 20. Yet, UC fails to explain why a state cannot raise revenue for its university system in the traditional methods available to states, such as raising taxes or selling bonds. Lilly submits that expanding the Eleventh Amendment to provide states with procedural advantages in litigation is not the best or even a rational way to promote a state's educational system.

Furthermore, UC fails to acknowledge its ability to sell or otherwise *assign* its patents to a private entity for valuable consideration and let *that* entity sue the alleged infringer in federal court. This Court has specifically held that an assignee has standing to sue an alleged infringer without the presence of the assignor in the lawsuit. *Waterman v. MacKenzie*, 138 U.S. 252, 255 (1891)(holding that an assignment of the "whole patent, comprising the exclusive right to make, use, and vend the invention . . . vests in the assignee . . . a right to sue infringers . . . in the name of the assignee alone"); *Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA*, 944 F.2d 870, 873-74 (Fed. Cir. 1991). By assigning its patents, UC can still collect revenue from its technical developments and avoid the alleged indignity of litigating in federal court.

On the other hand, if a state university sets aside its cloak of sovereign immunity in order to sue alleged infringers in federal court, it must be bound by the federal rules and applicable statutes. Any other rule would transform the state into a "super" litigant, enabling it to use its sovereign immunity

to dictate which rules and/or statutes it chooses to follow. Such a rule would seriously undermine principles of fundamental fairness critical to the proper operation of the federal courts by drastically increasing the power of states at the expense of other litigants.

Accordingly, UC is *not* entitled to choose the forum in which it will proceed to trial, but is *only* entitled to choose to stay out of the federal court system entirely. Once a state voluntarily enters the federal court system by *suing* another party, it loses its Eleventh Amendment protection and subjects itself to the same rules and statutes that apply to all other litigants, including 28 U.S.C. §§ 1404 and 1407. As aptly stated by the Federal Circuit, "Upon entering the litigation arena the Regents, like all litigants, become subject to the Federal Rules." (UC Pet. App. B at 52.)

Finally, UC contends that the Eleventh Amendment should preclude transfer to another venue because "the accused infringer could gain through a transfer motion what it could not accomplish through the early filing of a declaratory judgment action." (UC Pet. at 25.) UC's argument is a logical non sequitur. Assuming, as UC does, that Eleventh Amendment immunity would shield a state from a declaratory judgment action brought by a private citizen,[20] it necessarily follows that the citizen cannot pick the forum for a suit he or she is not

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[20] This issue of whether Congress has the power to abrogate a state's Eleventh Amendment immunity and subject it to suit under 35 U.S.C. §§ 271(h) of the patent laws is currently before the Federal Circuit as an appeal of Judge Dillin's decision in *Genentech, Inc. v. Regents of the University of California*, 939 F. Supp. 639, 646 (S.D. Ind. 1996). This question need not be addressed by the Court at this time because the Eleventh Amendment simply does not apply where the state is a willing plaintiff in federal court.

entitled to file. The state may thus stay out of federal court if it so chooses. If a state chooses, however, to enter the federal court system by voluntarily appearing as a plaintiff, then every defendant has the right to ask the federal court to conduct the litigation in a more convenient forum under 28 U.S.C. §§ 1404 and/or 1407, and the federal courts have acquired the authority over the state to make such decisions and issue appropriate orders effecting those decisions.

## CONCLUSION

For the foregoing reasons, Lilly urges the Court to deny UC's petition for a writ of certiorari in its entirety.

Respectfully submitted,

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In The

# Supreme Court of the United States

October Term, 1997

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,

*Petitioner,*

v.

ELI LILLY AND COMPANY,

*Respondent.*

**On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit**

## PETITIONER'S REPLY TO BRIEF IN OPPOSITION

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## I. BECAUSE *LEXECON* DECIDED THE CRUCIAL VENUE ISSUE AFTER THE *CERTIORARI* PETITION WAS FILED, A GVR ORDER IS WARRANTED[1]

Respondent cannot dispute that the self-transfer issue presented by Petitioner is nationally important since *Lexecon, Inc. v. Milberg Weiss Bershad, Hynes & Lerach*, No. 96-1482, 1998 U.S. LEXIS 1598 (Mar. 3, 1998), overruled all prior lower court decisions on the point. After *Lexecon*, Respondent also cannot deny that the federal district court in Indiana exceeded its authority in transferring to itself for trial on the merits Petitioner's cases that had been filed in the district court in California. *Lexecon* makes clear that "venue [in Indiana] is precluded by the governing statute." *Lexecon*, 1998 U.S. LEXIS 1598, at *28. Here, as in *Lexecon*, Congress left no discretion in the Indiana district court to transfer Petitioner's California litigation to itself for a trial on the merits. *Ibid.* Here, as in *Lexecon*, Petitioners continuously objected to the improper venue. Thus, here, as in *Lexecon*, remand to a proper forum is compelled.

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[1] Nothing in Respondent's conditional cross-petition dictates otherwise. It raises issues that have no bearing on those presented by the Regents. To the extent that those issues ever had any validity, they may be considered in due course by a new trial court on remand, as set out more fully in the Regents' brief in opposition filed concurrently herewith.

The *Lexecon* question is properly before this Court. Respondent mistakenly argues that Petitioner is foreclosed from raising the self-transfer venue error because (1) Petitioner did not specifically present the waiver issue as one of the questions presented to this Court, and (2) Petitioner had not properly headlined the Section 1407 aspect of its venue challenge in its opening brief on appeal to the Federal Circuit.

The question presented by Petitioner of whether 28 U.S.C. §§ 1404 and 1407(a) precluded self-transfer for trial on the merits necessarily subsumed the subsidiary issue of whether the Federal Circuit correctly addressed and decided this venue question. The propriety of the Federal Circuit's waiver determination need not have been presented as a separate question because it is "a necessary predicate to the resolution of the question presented in the petition." *Caspari v. Bohlen*, 510 U.S. 383, 389-390 (1994).[2] The alleged waiver issue here is "fairly within" the self-transfer question, *Lebron v. National R.R. Passenger Corp.*, 513 U.S. 374, 379 (1995), since it is "predicate to an intelligent resolution" of that question. *Caterpillar Inc. v. Lewis*, 117 S. Ct. 467, 476 n.13 (1996).

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[2] Respondent's reliance on *Izumi Seimitsu Kogyo Kabushiki Kaisha v. United States Philips Corp.*, 510 U.S. 27 (1993) and *Yee v. City of Escondido*, 503 U.S. 519 (1992) to foreclose Petitioner from raising the *Lexecon* point is misplaced. In both cases, petitioners tried to raise issues in their merits briefs that had not been addressed at all in their petitions for *certiorari*. Moreover, neither belatedly-presented issue was subsidiary to the questions raised in the respective petitions, as is the waiver question here.

This Court has never required litigants to undertake futile, expensive exercises to preserve their access to this Court on nationally important issues of law. The venue transfer issue was, at the very least, implicitly raised in Petitioner's opening brief on the merits to the Federal Circuit, and that issue was raised very explicitly in Petitioner's reply brief in the Federal Circuit. For Petitioner to have pressed the self-transfer argument more fervently in the Federal Circuit would have been futile: Every circuit and district court that had addressed the issue had upheld self-transfer under Section 1404(a).

Moreover, Respondent cannot claim unfair surprise or lack of an opportunity to be heard on the self-transfer issue. *Certiorari* had not been granted in *Lexecon* when this case was briefed before the Federal Circuit. After *certiorari* was granted in *Lexecon* and before oral argument, Petitioner promptly notified the Federal Circuit and Respondent. The Federal Circuit and Respondent were fully aware that Petitioner was challenging the validity of the self-transfer order, which was the subject of lively colloquy during oral argument. The propriety of the initial venue transfer had previously been presented to that court on Petitioner's petition for writ of mandamus in which Petitioner had expressed concern that if the initial transfer by the MDL panel was permitted, the Indiana court might further disregard Petitioner's choice of forum and its sovereignty by transferring the case to itself for trial. The Federal Circuit rejected Petitioner's contentions and dismissed Petitioner's worry about self-transfer as "speculative." Under these circumstances, no waiver of the venue question could properly be implied. *See Lexecon*, 1998 U.S. LEXIS 1598, at *17 n. 1 (rejecting

waiver arguments because efforts to request remand from MDL Panel would have been futile.)

Even if it were assumed, *arguendo*, that Petitioner did not adequately address the self-transfer venue issue before the Federal Circuit, this case is nevertheless appropriate for exercise of the Court's GVR power. In particular, this Court properly issues a GVR order when the law has changed after the lower court's decision was entered. *Stutson v. United States*, 516 U.S. 193, 195-96 (1996); *Lawrence v. Chater*, 516 U.S. 163, 166-67 (1996). *Cf. Youakim v. Miller*, 425 U.S. 231, 235 (1976) (remanding case for consideration of issue that had not been raised below, because interpretation of statute involved had been changed in the interim); *Hormel v. Helvering*, 312 U.S. 552, 558-59 (1941) (affirming circuit court's consideration of issue not raised before Board of Tax Appeals where hearing occurred before relevant Supreme Court decision handed down, and remanding issue to Board of Tax Appeals.)[3] The Court has "GVR'd in light of a wide range of developments, including our own decisions . . . . " *Lawrence*, 516 U.S. at 166. That order alleviates the " 'potential for unequal treatment' that is inherent in [the Court's] inability to grant plenary review of all pending

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[3] *See also Mitchell v. Forsyth*, 472 U.S. 511, 530 (1985) ("purely legal question" appropriate for review although not fully considered below); *Uebersee Finanz-Korporation, A.G. v. McGrath*, 343 U.S. 205, 212-13 (1952) (judgment against petitioner vacated because Act involved reinterpreted in another case decided the same day); *Vandenbark v. Owens-Illinois Glass Co.*, 311 U.S. 538, 543 (1941) (intervening judicial decisions merits reversal of judgments correct when entered).

cases raising similar issues . . . . " *Id.* at 167. (Citations omitted).

## II. IF THE DECISION BELOW IS VACATED AND THE CAUSE REMANDED, NO OTHER QUESTION PRESENTED NEED BE REACHED

*Lexecon* teaches that Congress requires cases transferred under § 1407(a) to be remanded to the originating district court for a new trial on the merits when a transferee court has improperly tried a transferred case on the merits after pretrial proceedings have concluded. As this Court stated, "the substantiality of the protected interest [to be tried in the transferor court] is attested by a congressional judgment that in the circumstances described in the statute no discretion is to be left to a court faced with an objection to a statutory violation." *Lexecon*, 1998 U.S. LEXIS 1598, at *28. Petitioner's right, as plaintiff and sovereign, to choose its forum would be thereby respected, albeit after great delay and expense. Although the first and third questions presented here are properly before the Court, the damage to Petitioner from the errors in deciding these questions is prospectively undone if the case is ultimately remanded to California for a new trial.

WHEREFORE, Petitioner prays for an order granting *certiorari*, vacating the judgment below, and remanding the case to the Court of Appeals for the Federal Circuit for further consideration in light of *Lexecon, Inc. v. Milberg Weiss Bershad, Hynes & Lerach*, No. 96-1482, 1998 U.S. LEXIS 1598 (Mar. 3, 1998).

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(4)

No. 97-1201

IN THE

# Supreme Court of the United States

OCTOBER TERM, 1997

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,

*Petitioner,*

v.

ELI LILLY AND COMPANY,

*Respondent.*

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit**

## RESPONDENT'S SUPPLEMENTAL BRIEF IN OPPOSITION

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## PARTIES TO THE PROCEEDING BELOW

The parties are Petitioner, Regents of the University of California, and Respondent, Eli Lilly and Company. Eli Lilly and Company possesses neither a parent company nor any non-wholly owned subsidiaries.

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## I. INTRODUCTION

Subsequent to the filing of Lilly's Brief in Opposition to the Regents of the University of California's Petition for a Writ of Certiorari, this Court decided *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 118 S. Ct. 956 (1998). In *Lexecon*, the Court held that a judge presiding over a multidistrict litigation could not "self-transfer" a case to the multidistrict forum pursuant to the express language of 28 U.S.C. § 1407. Accordingly, respondent Eli Lilly and Company ("Lilly"), pursuant to this Court's Rule 15.8, submits this supplemental brief in order to address the effect of the Court's decision in *Lexecon* on UC's pending petition.[1]

As will be discussed below, the *Lexecon* decision should have no bearing on this case. The Federal Circuit specifically held that the Regents of the University of California ("UC") *waived* the *Lexecon* venue issues. Moreover, UC failed to properly raise the waiver issue in the "Question Presented" in its petition before this Court. Thus, UC's suggestion that this Court should grant certiorari, vacate the lower judgment, and remand ("GVR") is inappropriate under these circumstances. UC has already failed to properly raise the issue before both this Court and the Federal Circuit and no further proceedings are needed to dispose of UC's petition.

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[1] *See* Robert L. Stern et al., *Supreme Court Practice*, 377 (7th ed. 1993)(stating with regard to supplemental briefs that "the Court wants such briefs to be filed in order to be advised of new factors that may affect its consideration of the case.")

## II. THE COURT'S DECISION IN LEXECON HAS NO BEARING ON THE INSTANT CASE

### A. UC Waived the *Lexecon* Issue in the Lower Courts

UC asserts that it "continuously objected to the improper venue[,]" and thus "as in *Lexecon*, remand to a proper forum is compelled." (UC Reply Br. at 1.) The fundamental defect in UC's argument, however, is that UC did *not* continuously challenge the propriety of the self-transfer under § 1407, as did the petitioner in *Lexecon*. Instead, UC *failed* properly to raise this issue at all. In direct contrast to the instant case, the petitioner in *Lexecon* sought a writ of mandamus from the Ninth Circuit *immediately* after the improper self-transfer, asserting that the multidistrict court's self-transfer contradicted the express language of § 1407. Moreover, the *Lexecon* petitioner again raised on appeal to the Ninth Circuit the validity of the self-transfer. Due to these efforts to preserve the § 1407 issue, the Court required remand in the *Lexecon* case because:

> the § 1407(a) mandate would lose all meaning if a party who continuously objected to an uncorrected categorical violation of the mandate could obtain no relief at the end of the day.

*Lexecon*, 118 S. Ct. at 966. Yet, *unlike* the petitioner in *Lexecon*, UC failed to assert before the district court that § 1407 precluded it from transferring the case to the Southern District of Indiana, failed to raise the § 1407 issue on mandamus to the Federal Circuit after the district court ordered the transfer, and failed to raise the issue in its principal brief on the merits before the Federal Circuit. While UC did challenge whether the transfer violated the Eleventh Amendment and

whether Judge Dillin properly evaluated the statutory criteria set forth in 28 U.S.C. § 1404, it did not allege that the plain language of § 1407 required remand. Because UC never raised the venue defect under § 1407 at a time when the trial court could have cured the defect, and thereby have avoided an unnecessary trial, and because UC failed to raise the § 1407 issue in its principal brief on appeal, UC waived this venue issue, as specifically found by the Federal Circuit.

Moreover, as stated on pages 21-22 of Lilly's brief in opposition, UC's raising of a § 1404 venue issue and an Eleventh Amendment venue issue does not fairly include the § 1407 venue issue for the same reason that raising a physical taking claim does *not* fairly include a regulatory taking claim. *Yee v. Escondido*, 503 U.S. 519, 537 (1992). While the § 1404, § 1407, and Eleventh Amendment challenges to venue are all subsidiary to the question of "was venue proper?"—as in *Yee*, "they exist side by side, neither encompassing the other." *Id.*

In view of the foregoing, UC's proposed remedy of GVR would be a waste of the resources of this Court and the Federal Circuit. The Federal Circuit has *already* determined that the issue has been waived. Indeed, it is this very fact that distinguishes the instant case from the authority cited by UC at page 4 of its Reply Brief. In not one of UC's cited cases did the Court of Appeals explicitly hold that the party waived the issue upon which the Court granted a GVR.[2] Moreover, this Court held—and UC does not challenge—that the venue concerns

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[2] For example, *Hormel v. Helvering*, 312 U.S. 552, 555 (1941), involved a situation where the appellate court affirmatively chose to decide an issue not raised before the Board of Tax Appeals. The facts of *Hormel*, however, have no bearing on the instant case where the appellate court, the Federal Circuit, affirmatively held that UC waived the *Lexecon* issue and thus did not consider it.

raised by UC are indeed waivable. *See Olberding v. Illinois Central R. Co.*, 346 U.S. 338, 340 (1953)(holding that venue is "a limitation designed for the convenience of litigants, and, as such, may be waived by them"), *cited in Lexecon*, 118 S. Ct. at 965; *Leroy v. Great Western United Corp.*, 443 U.S. 173, 180 (1979)(stating that personal jurisdiction and venue may be waived by the parties).

B. UC Failed Properly to Raise the Waiver Issue Before this Court

To warrant remand, this Court would first need to determine that the Federal Circuit's waiver determination was erroneous. However, as discussed at pages 16-19 of Lilly's brief in opposition, this issue is not now before the Court because UC failed to raise the waiver issue as one of its questions presented, as required by Rule 14.1(a). *Izumi Seimitsu Kogyo Kabushiki Kaisha v. U.S. Philips Corp.*, 510 U.S. 27, 31-32 (1993). In a flawed attempt to distinguish *Izumi*, UC argues that the petitioner in *Izumi* tried to raise issues in its merits brief that had not been addressed "at all" in its petition for *certiorari*. (UC Reply Br. at 2 n.2) In making this statement, UC ignores the facts of *Izumi*. The Court specifically found that Izumi *did* discuss the issue in its *certiorari* petition but held, nevertheless, that it was still *not* properly before the Court. The Court plainly stated that "the fact that Izumi discussed this issue in the text of its petiton for certiorari does not bring it before us." 510 U.S. at 32.[3] Accordingly, the fact that UC discussed the Federal Circuit's

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[3] In fact, the dissent pointed out that Izumi's petition "devoted an entire section" on the intervention issue, the issue which the majority held was not presented as a question and thus would not be addressed by the Court. 510 U.S. at 35.

finding of waiver in its certiorari petition does *not* bring it before this Court.

Moreover, contrary to UC's assertions (UC Reply Br. at 2), the waiver issue is *not* fairly included in UC's second question presented. As was the case in *Izumi*, the waiver issue is a threshold inquiry which in no way depends on the merits of the underlying issue and is analytically distinct from whether the statutory language of § 1407 precludes self-transfer. Furthermore, the question of whether the Federal Circuit correctly found that UC had waived the issue is unlikely to establish a new principle of law and is not worthy of this Court's attention. Indeed, the Federal Circuit's decision that UC waived an issue not presented in opening brief is amply supported by precedent and is consistent with the practice of many United States Courts of Appeals. (*See* Lilly Opp. Br. at 20.)

Since the Federal Circuit found that UC waived the *Lexecon* issue, since UC failed to properly raise the validity of this aspect of the Federal Circuit's decision before this Court, and since the Federal Circuit was indeed correct that UC effectuated a waiver, UC's proposed remedy of GVR should be rejected and UC's petition should be denied.

## III. CONCLUSION

For the foregoing reasons, and the reasons set forth in Lilly's Opposition Brief, Lilly urges the Court to deny UC's petition in its entirety.

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